UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re: Seroquel XR (Extended Release Quetiapine Fumarate) Antitrust Litigation	Master Dkt No. 20-1076-CFC
This Document Relates To: All Direct Purchaser Class Actions	**JURY TRIAL DEMANDED**

CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

Plaintiffs J M Smith Corporation d/b/a, Smith Drug Company and KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. ("Plaintiffs"), on behalf of themselves and all others similarly situated, bring this Class Action Complaint against AstraZeneca Pharmaceuticals L.P.; AstraZeneca L.P. (collectively, "AstraZeneca"); Handa Pharmaceuticals, LLC ("Handa"); and Par Pharmaceutical, Inc. ("Par") (together, AstraZeneca, Handa and Par are "Defendants"), for Defendants' violations of the antitrust laws concerning the pharmaceutical drug Seroquel XR® (quetiapine fumarate extended-release tablets) ("Seroquel XR"). Based on (a) personal knowledge, (b) the investigations of counsel, and (c) information and belief, Plaintiffs allege:

I. NATURE OF THE ACTION

1. This is a civil antitrust action seeking treble damages arising out of Defendants' anticompetitive conduct that delayed generic competition in the United States and its territories for Seroquel XR, a prescription drug product approved by the U.S. Food and Drug Administration ("FDA") in the United States for (1) add-on treatment to an antidepressant for patients with major depressive disorder ("MDD") who did not have an adequate response to antidepressant therapy; (2) acute depressive episodes in bipolar disorder; (3) acute manic or mixed episodes in bipolar disorder alone or with lithium or divalproex; (4) long-term treatment of bipolar disorder with lithium or divalproex; and (5) schizophrenia. Plaintiffs seek overcharge damages arising from AstraZeneca's unlawful agreements with Handa and Accord Pharmaceuticals, Inc. ("Accord") not to compete in the market for Seroquel XR and corresponding generic versions thereof in the United States.[1] As set forth below, Handa subsequently assigned this unlawful agreement to Par, which performed the agreement, sold generic Seroquel XR at supracompetitive prices, and shared the illicit gains with Handa.

2. Prior to the market entry of generic versions of Seroquel XR, AstraZeneca's U.S. sales of branded Seroquel XR exceeded $1 billion annually.

[1] "United States" is defined herein to include the United States, its territories, possessions, and the Commonwealth of Puerto Rico.

3. Generic manufacturers Handa and Accord recognized the huge market potential for generic versions of Seroquel XR and, between June and December of 2008, each became the first generic drug maker to file an Abbreviated New Drug Application ("ANDA") with the FDA seeking approval to market certain strengths of generic extended-release quetiapine fumarate tablets. Handa was the first to submit an ANDA (No. 90-482) for the 50mg, 150mg, 200mg and 300mg strengths of extended-release quetiapine fumarate tablets, with Seroquel XR as its Reference Listed Drug.[2] On June 18, 2008, Accord became the first generic drug maker to file an ANDA (No. 90-681) for the 400mg strength of extended-release quetiapine fumarate tablets, with Seroquel XR as the Reference Listed Drug.[3] Handa filed an ANDA for the 400mg strength thereafter.[4]

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[2] *See* Final Approval Letter from Carol Holquist, Deputy Director, Office of Regulatory Operations, FDA, to Meredith Selby, Senior Director, Regulatory Affairs, at Par Pharmaceutical Inc., at 2 (May 9, 2017), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/090482Orig1s000ltr.pdf.

[3] *See* Final Approval Letter from Carol Holquist, Deputy Director, Office of Regulatory Operations, FDA, to Sabita Nair, Senior Director, Regulatory Affairs, Accord Healthcare Inc., at 2 (Nov. 1, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/090681Orig1s000TAltr.pdf; FDA, Paragraph IV Patent Certifications (Dec. 1, 2020), https://www.fda.gov/media/133240/download.

[4] *See* Final Approval Letter from Carol Holquist, Deputy Director, Office of Regulatory Operations, FDA, to Meredith Selby, Senior Director, Regulatory Affairs, at Par Pharmaceutical Inc., at 2 (May 9, 2017), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/090482Orig1s000ltr.pdf.

4. Pursuant to 21 U.S.C. § 355(j)(2)(B), Handa sent AstraZeneca four separate Paragraph IV notice letters dated July 10, 2008, July 23, 2008, October 16, 2008, and November 14, 2008.[5] Accord sent AstraZeneca two separate Paragraph IV notice letters dated September 5, 2008 and January 23, 2009.[6] In the Paragraph IV notice letters, Handa and Accord each certified that they would seek final FDA approval to market, and intended to launch, their generic Seroquel XR products prior to the expiration of the follow-on patent purportedly covering Seroquel XR, U.S. Patent No. 5,948,437 (the "'437 Patent"), which Handa and Accord claimed was invalid and/or would not be infringed by Handa's and Accord's respective proposed generic Seroquel XR products.

5. The '437 Patent expired on May 28, 2017.

6. On July 28, 2008, AstraZeneca filed a complaint against Handa in the United States District Court for the District of New Jersey, alleging that Handa's filing of its ANDA No. 90-482 relating to its 200mg, 300mg and 400mg strengths of generic Seroquel XR infringed the '437 Patent under 35 U.S.C. § 271(e)(2)(A).[7]

7. On October 28, 2008, AstraZeneca filed a complaint against Handa in the United States District Court for the District of New Jersey, alleging that Handa's

[5] Stipulated Facts ¶ 26, ECF No. 156-1, *AstraZeneca Pharmaceuticals et al. v. Handa Pharmaceuticals LLC*, 3:10-cv-01835-JAP-TJB (D.N.J.).

[6] *Id.* ¶ 27.

[7] *Id.* ¶ 34.

filing of its ANDA No. 90-482 relating to its 50mg strength of generic Seroquel XR infringed the '437 Patent under 35 U.S.C. § 271(e)(2)(A).[8]

8. On December 8, 2008, AstraZeneca filed a complaint against Handa in the United States District Court for the District of New Jersey, alleging that Handa's filing of its ANDA No. 90-482 relating to its 150mg strength of generic Seroquel XR infringed the '437 Patent under 35 U.S.C. § 271(e)(2)(A).[9]

9. The foregoing three lawsuits filed by AstraZeneca against Handa were consolidated, and are collectively referred to herein as the "Handa Seroquel XR Patent Litigation."

10. AstraZeneca filed two patent infringement lawsuits against Accord regarding the two Accord Paragraph IV certification notice letters. First, on September 26, 2008, AstraZeneca filed civil action no. 08-cv-04804 against Accord in the District of New Jersey in connection with Accord's notice letter dated September 5, 2008.[10] Second, on February 10, 2009, AstraZeneca filed civil action no. 09-cv-00619 against Accord in the District of New Jersey in connection with Accord's notice letter dated January 23, 2009. These lawsuits against Accord are collectively referred to as the "Accord Seroquel XR Patent Litigation."

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[8] *Id.* ¶ 35.

[9] *Id.* ¶ 36.

[10] *Id.* ¶¶ 37-38.

11. Over the course of the Handa Seroquel XR Patent Litigation, it became clear that Handa's proposed generic version of Seroquel XR would not infringe the '437 Patent. The '437 Patent did not broadly claim the chemical compound quetiapine, or even its salt quetiapine fumarate. Instead, the '437 Patent narrowly claimed very specific formulations of quetiapine fumarate, each of which requires a "gelling agent." The Honorable Joel A. Pisano, who presided over the Accord Seroquel XR Patent Litigation and the Handa Seroquel XR Patent Litigation, construed "gelling agent" to mean "any substance which forms a gel when in contact with water." But Handa's proposed generic version of Seroquel XR used hydrogenated vegetable oil, which is hydrophobic, not even miscible with water, *i.e.,* it does not form a homogeneous mixture with water, and not a "gelling agent" under the district court's claim construction.

12. The District Court issued a claim construction opinion applicable in both the Handa Seroquel XR Patent Litigation and the Accord Seroquel XR Patent Litigation on November 30, 2010.

13. On December 9, 2010, the FDA granted tentative approval to Handa's ANDA for generic Seroquel XR in all strengths, determining that Handa's ANDA for generic Seroquel XR was approvable and satisfied all bioequivalence; chemistry,

manufacturing, and controls ("CMC"); and labeling requirements.[11] The approval was not final due to the Handa Seroquel XR Patent Litigation as filed by AstraZeneca which resulted in a regulatory-imposed 30-month stay on the ability of FDA to grant final approval (the 30 month period commencing upon the filing of the lawsuits in 2008).

14. Under the District Court's claim construction, AstraZeneca was very likely to lose the litigation over the '437 Patent. Rather than face the risk that Handa's proposed generic versions of Seroquel XR would be found not to infringe the '437 Patent, AstraZeneca induced Handa with a large "reverse payment" (*i.e.*, a payment from the patent holder, AstraZeneca, to the alleged infringer, Handa), to quit the patent fight and not compete with AstraZeneca for up to five years.

15. Specifically, on or about September 29, 2011, and after a period of negotiation, AstraZeneca and Handa entered into a settlement agreement concerning Handa's ANDA No. 90-482 (the "Handa Non-Compete Agreement").[12] Under the

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[11] *See* Tentative Approval Letter from Keith Webber, Deputy Director Office of Pharmaceutical Science, FDA, to Maggie Chang, Executive Vice President, Quality Affairs, Handa Pharmaceuticals, LLC, at 1 (Dec. 9, 2010), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/090482s000ltr.pdf .

[12] *See US District Court Finds SEROQUEL XR Formulation Patent Valid and Infringed* (Mar. 29, 2012), https://www.businesswire.com/news/home/20120329006628/en/District-Court-Finds-SEROQUEL-XR-Formulation-Patent ("On September 29, 2011, AstraZeneca

terms of the Handa Non-Compete Agreement, Handa agreed to quit the patent fight and delay its launch of generic extended-release quetiapine fumarate in the 50mg, 150mg, 200mg, 300mg strengths until November 1, 2016 (and also agreed to quit the patent fight as to the 400mg strength as well, for which Handa was not the first filer). In exchange for Handa's delayed generic launch, AstraZeneca agreed not to compete with Handa by launching an authorized generic Seroquel XR (the brand product packaged and sold as a less-expensive generic, sometimes referred to as an "AG") during the first 180 days after Handa's launch, *i.e.*, between November 1, 2016 and April 30, 2017. Upon information and belief, Handa also acquired the right to obtain generic product from AstraZeneca to sell as its own for at least a 180-day period commencing November 1, 2016.

16. But for the Handa Non-Compete Agreement, Handa would not have agreed to delay launching 50mg, 150mg, 200mg, 300mg strengths of generic Seroquel XR until November 1, 2016 (which included delaying its pursuit of final approval for its ANDA regarding these strengths and commercial manufacturing thereof) and AstraZeneca would not have agreed to delay launching an authorized generic in these strengths to compete with Handa's generic product until May 1, 2017. The purpose and effect of the Handa Non-Compete Agreement was to delay

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granted Handa a license to the 5,948,437 patent effective November 1, 2016, or earlier under certain circumstances.").

lower-priced generic competition with AstraZeneca's branded Seroquel XR product for up to five years, and to eliminate competition for generic extended-release quetiapine fumarate from an AG in the 50mg, 150mg, 200mg, 300mg strengths during Handa/Par's 180-day period of generic exclusivity (as described below), thereby generating enormous windfalls for AstraZeneca and Handa (and eventually Par).

17. On October 29, 2012, Par announced that it had acquired Handa's ANDA No. 90-482.[13] Par's press release stated that it:

> entered into an exclusive acquisition and license agreement with Handa Pharmaceuticals, LLC to acquire Handa's Abbreviated New Drug Application (ANDA) for quetiapine fumarate extended-release tablets, the generic version of AstraZeneca's Seroquel XR®. Handa believes it is the first applicant to file an ANDA containing a paragraph IV certification for the 50 mg, 150 mg, 200 mg and 300 mg strengths of the product, which would potentially provide 180 days of marketing exclusivity . . . .
>
> Under the terms of the agreement, Par has made a payment for the ANDA and for exclusive rights to market, sell and distribute quetiapine fumarate extended-release tablets in the U.S. under the ANDA, subject to its final approval by the U.S. Food and Drug Administration. Par will receive a share of profits from the sales of the product. Under the terms of a prior settlement agreement with AstraZeneca, which has been assigned to Par, Par has a license to enter the U.S. market with quetiapine fumarate extended-release tablets on November 1, 2016 or earlier under certain circumstances.

[13] *See Par Pharmaceutical Acquires Rights to Market and Distribute Generic Seroquel XR® in the U.S.* (Oct. 29, 2012), https://www.prnewswire.com/news-releases/par-pharmaceutical-acquires-rights-to-market-and-distribute-generic-seroquel-xr-in-the-us-176239031.html.

18. A press release Handa issued on May 10, 2017 confirms that Handa and Par agreed, as part of their acquisition and license agreement, to share in the illicit profits from the Handa Non-Compete Agreement. The press release states, "Par's Quetiapine XR ANDA was developed by Handa and acquired by Par on August 3, 2012. Handa retains the right to a portion of profits from the sale of the product, pursuant to its agreement with Par."[14] By acquiring Handa's ANDA, acquiring an assignment of the Handa Non-Compete Agreement, agreeing to divide the illicit gains therefrom, performing the delay provisions thereof, and selling generic Seroquel XR at supracompetitive prices, Par became an active participant and co-conspirator in the pre-existing conspiracy between Handa and AstraZeneca and Par is, like Handa and AstraZeneca, jointly and severally liable for all harm flowing from it.

19. On information and belief, Accord and AstraZeneca entered into an agreement similar to the Handa Non-Compete Agreement, which included a similar reverse payment from the patent holder, AstraZeneca, to the alleged infringer, Accord, to quit the patent fight and not compete with AstraZeneca for up to five

[14] *Handa Pharmaceuticals, Inc. Announces FDA Approval for Generic Version of AstraZeneca's SEROQUEL XR® Extended Release Tablets* (May 10, 2017), https://handapharma.com/handa-pharmaceuticals-inc-announces-fda-approval-for-generic-version-of-astrazenecas-seroquel-xr-extended-release-tablets/.

years. Specifically, on or about October 5, 2011,[15] prior to the end of any trial, Accord and AstraZeneca entered into an agreement pursuant to which Accord agreed to delay its launch of the 400mg strength of generic Seroquel XR, for which Accord was the first ANDA filer, until November 1, 2016, and AstraZeneca agreed to not launch an authorized generic version of the 400mg strength for 180 days thereafter. Pursuant to this agreement, Accord in fact did not launch its generic 400mg Seroquel XR product until November 1, 2016, and AstraZeneca did not launch an authorized generic version of Seroquel XR 400mg until May 1, 2017. The Accord-AstraZeneca settlement agreement is referred to as the "Accord Non-Compete Agreement."

20. But for the Accord Non-Compete Agreement, Accord would not have agreed to delay launching the 400mg strength of generic Seroquel XR until November 1, 2016 (which included delaying its pursuit of final approval for its ANDA regarding these strengths and commercial manufacturing thereof) and AstraZeneca would not have agreed to delay launching an authorized generic in this strength to compete with Accord's generic product until May 1, 2017. The purpose and effect of the Accord Non-Compete Agreement was to delay lower-priced

[15] *AstraZeneca enters into a settlement agreement with Accord Healthcare, Inc. and Intas Pharmaceuticals Ltd regarding US SEROQUEL XR® patent litigation* (Oct. 5, 2011), https://www.astrazeneca.com/media-centre/press-releases/2011/AstraZeneca-enters-into-a-settlement-agreement-with-Accord-Healthcare-Inc-and-Intas-Pharmaceuticals-Ltd-regarding-US-SEROQUEL-XR-patent-litigation-05102011.html#modal-historic-confirmation.

generic competition with AstraZeneca's branded Seroquel XR product for up to five years, and to eliminate competition for generic extended-release quetiapine fumarate from an AG during Accord's 180-day period of generic exclusivity, thereby generating enormous windfalls for AstraZeneca and Accord.

21. On November 1, 2016, Par began selling 50mg, 150mg, 200mg, 300mg generic Seroquel XR and Accord began selling 400mg generic Seroquel XR.[16]

22. On May 1, 2017 (180 days later), AstraZeneca launched authorized generic versions of Seroquel XR in the 50mg, 150mg, 200mg, 300mg, and 400mg strengths.[17]

23. Several other generic competitors launched their own versions of generic Seroquel XR (in all strengths) in or around early May 2017.

24. Because of the unlawful Handa Non-Compete Agreement and Accord Non-Compete Agreement (together, the "Non-Compete Agreements"), no less-expensive generic Seroquel XR was available for Plaintiffs and other members of the Class (defined below) to purchase in the United States until November 1, 2016

[16] *See, e.g.*, OptumRx, Seroquel XR (quetiapine) – First Time Generic, https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/new-generics/newgenerics_seroquelxr_2016-1102.pdf.

[17] *See* DailyMed, LABEL: QUETIAPINE FUMARATE EXTENDED RELEASE, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7283b14f-023d-466f-a7eb-4356803d7c65&audience=consumer (showing AstraZeneca with a May 1, 2017 launch date as an "NDA Authorized Generic").

and, for a period of six months thereafter, there was only one generic available for each strength of Seroquel XR (marketed by Par in the 50mg, 150mg, 200mg, and 300mg strengths and by Accord in the 400mg strength) instead of two, which would have driven down the costs of the generics during that 180-day period.

25. But for the unlawful Non-Compete Agreements, one or more generic versions of Seroquel XR (in each strength) would have entered the market much earlier – either following patent litigation victory by Handa and/or Accord, launch(es) by Handa and/or Accord while patent litigation remained pending (sometimes referred to as launching "at risk"), or via agreement(s) that did not include unlawful reverse payments from AstraZeneca for delay. Courts have repeatedly recognized that large reverse payments result in later generic entry dates than what would otherwise occur. *See, e.g.*, *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751-52 (E.D. Pa. 2014). In addition, AstraZeneca would have simultaneously launched authorized generic Seroquel XR (in each strength) when generic entry occurred instead of waiting 180 days (as AstraZeneca actually did). Thus, absent the unlawful Non-Compete Agreements, Plaintiffs and members of the Class would have been able to satisfy their requirements for extended-release quetiapine fumarate at significantly lower prices substantially earlier.

26. By and through the Non-Compete Agreements, AstraZeneca, Handa/Par and Accord agreed to divide ill-gotten revenues, both during the period

in which Handa/Par and Accord agreed not to launch (*i.e.*, prior to November 1, 2016), and during the first 180 days after Handa/Par's and Accord's launch of their respective generics during which AstraZeneca agreed not to launch authorized generic Seroquel XR to compete with Handa/Par's and Accord's respective generic products, all of which resulted in anticompetitive overcharges to Plaintiffs and members of the Class.

27. Defendants thus violated Sections 1 and 2 of the Sherman Act through the anticompetitive Non-Compete Agreements that allocated markets, restricted output, and improperly maintained, enhanced and extended AstraZeneca's market and monopoly power by (1) foreclosing or delaying competition from lower-priced generic Seroquel XR that otherwise would have entered the market earlier; (2) foreclosing or delaying competition from authorized generic Seroquel XR that otherwise would have entered the market earlier; and (3) fixing, raising, maintaining, or stabilizing the prices of Seroquel XR and its generic equivalents at supracompetitive levels.

28. Plaintiffs and all others similarly situated were injured and sustained damages in the form of overcharges for branded and generic forms of Seroquel XR as a direct result of the unlawful Non-Compete Agreements. Plaintiffs, on behalf of the Class (defined below), file this suit to recover these overcharges (trebled).

II. JURISDICTION AND VENUE

29. This Complaint is filed and these proceedings are instituted under Section 4 of the Clayton Act, 15 U.S.C. § 15(a), to recover treble damages and the costs of suit, including reasonable attorneys' fees, for the injuries Plaintiffs and members of the Class sustained because of Defendants' violations, as herein alleged, of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2. This Court's jurisdiction is based upon 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15.

30. Defendants transact business within this judicial district, and Defendants' interstate trade and commerce hereinafter described was and is carried out, in substantial part, in this district. Venue, therefore, is appropriate within this district under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c). Moreover, in earlier motions practice, Defendants stated that venue was appropriate in this District.

31. Defendants' conduct, as described in this Complaint, was within the flow of, was intended to, and did have a substantial effect on, the interstate commerce of the United States, including in this District.

32. During the Class Period (defined below), AstraZeneca and Par manufactured, sold, and/or shipped Seroquel XR and/or generic Seroquel XR in a continuous and uninterrupted flow of interstate commerce. The contract and conspiracy in which Defendants participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

33. During the Class Period, each Defendant, or one or more of its affiliates, used the instrumentalities of interstate commerce to join or effectuate the Non-Compete Agreements and conspiracy.

34. This Court has personal jurisdiction over each Defendant because each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of its illegal conduct and conspiracy throughout the United States, including in this District. The conduct and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District. Moreover, in earlier motions practice, Defendants stated that this Court would have personal jurisdiction over Defendants.

III. THE PARTIES

35. Plaintiff J M Smith Drug Corporation d/b/a Smith Drug Company ("Smith Drug Company") is a corporation organized under the laws of the State of South Carolina and is located at 9098 Fairforest Road, Spartanburg, South Carolina 29301. Smith Drug Company purchased branded Seroquel XR and generic Seroquel XR directly from AstraZeneca and Par respectively during the Class Period (defined below), and was injured by the illegal conduct described herein.

36. Plaintiff KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. is a corporation organized under the laws of the State of New York, with headquarters

in Gouverneur, New York. KPH operates retail and online pharmacies in the Northeast under the name Kinney Drugs, Inc. KPH is the assignee of McKesson Corporation, who directly purchased branded Seroquel XR and generic Seroquel XR directly from AstraZeneca and Par respectively during the Class Period (defined below), and was injured by the illegal conduct described herein. As a result of Defendants' alleged anticompetitive conduct, KPH paid supracompetitive prices for its branded and generic Seroquel XR purchases and was injured by the illegal conduct alleged herein.

37. Defendant AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of Delaware, with a principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

38. Defendant AstraZeneca LP is a Delaware limited partnership with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

39. Defendant AstraZeneca UK Limited is a company operating and existing under the laws of the United Kingdom, with its principal place of business at 15 Stanhope Gate, London, United Kingdom W1Y 6LN.

40. Defendant Handa Pharmaceuticals, LLC is a limited liability corporation organized under the laws of California, with a principal place of business at 1732 N. 1st Street, Suite 200, San Jose, California 95112.

41. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business at One Ram Ridge Road, Chestnut Ridge, New York 10977.

42. All of Defendants' actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or undertaken by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with Defendants' actual and/or apparent authority.

IV. CLASS ACTION ALLEGATIONS

43. Plaintiffs bring this action on behalf of themselves and, under Federal Rule of Civil Procedure 23(a) and (b)(3), as representatives of a class of direct purchasers (the "Class" or "Direct Purchaser Class") defined as follows:

> All persons or entities in the United States, including its territories, possessions, and the Commonwealth of Puerto Rico, who purchased brand or generic Seroquel XR directly from any of the Defendants at any time from August 2, 2015 until the effects of Defendants' conduct ceases (the "Class Period"). Excluded from the Class are Defendants and their officers, directors, management and employees, predecessors, subsidiaries and affiliates, and all federal governmental entities.

44. Members of the Direct Purchaser Class are so numerous and/or geographically dispersed that joinder is impracticable. While the exact number of Class members is unknown to Plaintiffs, it is believed to be sufficiently numerous.

The Class is readily identifiable from information and records in Defendants' possession.

45. Plaintiffs' claims are typical of members of the Class. Plaintiffs and all members of the Class were damaged by the same wrongful conduct by Defendants, *i.e.*, Defendants' anticompetitive conduct deprived the Class members of the benefits of competition from less-expensive generic Seroquel XR, causing them to pay artificially inflated, supracompetitive prices for brand and generic Seroquel XR.

46. Plaintiffs will fairly and adequately protect and represent the interests of the Class. Plaintiffs' interests are coincident with, and not antagonistic to, those of the Class.

47. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and particularly class action antitrust litigation in the pharmaceutical industry.

48. Questions of law and fact common to members of the Class predominate over questions, if any, that may affect only individual Class members, because Defendants have acted on grounds generally applicable to the entire Class. Such generally applicable questions are inherent in Defendants' wrongful conduct.

49. Questions of law and fact common to the Class include:

a. whether the conduct alleged herein constitutes a violation of the antitrust laws;

b. whether Defendants conspired to suppress generic competition to Seroquel XR;

c. whether Defendants' challenged conduct suppressed generic competition to Seroquel XR;

d. whether a relevant antitrust market needs to be defined in this case in light of the existence of direct proof of AstraZeneca's power to exclude generic competition and charge supracompetitive prices for Seroquel XR and/or the *per se* illegal nature of the challenged conduct;

e. if a relevant antitrust market needs to be defined, what the definition of the relevant antitrust market for analyzing AstraZeneca's monopoly power is, and whether AstraZeneca had monopoly power in the relevant antitrust market;

f. whether AstraZeneca illegally obtained or maintained monopoly power in the relevant market;

g. whether Defendants' actions constituted a *per se* illegal market allocation or output restriction agreement, or whether Defendants' actions are subject to the antitrust rule of reason;

h. whether Defendants' actions were, on balance, unreasonable restraints of trade;

i. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;

j. whether, and to what extent, Defendants' conduct caused antitrust injury (overcharges) to Plaintiffs and the Direct Purchaser Class; and

k. the quantum of overcharge damages paid by the Class in the aggregate.

50. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Among other things, class treatment will permit a

large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that could not be practicably pursued individually, substantially outweighs potential difficulties in management of this class action.

51. Plaintiffs know of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

V. REGULATORY BACKGROUND

A. The Regulatory Structure for Approval of Drugs

52. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), a company seeking to market a new drug must obtain the approval of the FDA by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-92. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as information on applicable patents. 21 U.S.C. §§ 355(a), (b).

53. When the FDA approves a brand manufacturer's NDA, the brand manufacturer may list in the FDA's book of Approved Drug Products with Therapeutic Equivalence Evaluations (called the "Orange Book") any patent that it certifies (1) claims either the approved drug product or approved methods of using

the drug product, and (2) could reasonably be asserted against a generic manufacturer who makes, uses, or sells the drug product without authorization prior to the expiration of the listed patent(s). Relevant patents issued after NDA approval must be listed in the Orange Book within 30 days of issuance. 21 U.S.C. §§ 355(b)(1), (c)(2).

54. The FDA relies completely on the brand manufacturer's certification about its patents, as the FDA does not have the resources or authority to verify for accuracy or trustworthiness whether those patents are valid and enforceable, and actually cover the drug product or its use. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

1. The Hatch-Waxman Amendments

55. In 1984, Congress enacted the Hatch-Waxman Amendments to the FDCA to expedite the entry of less expensive generic competitors to brand drugs to reduce healthcare expenses nationwide, while also providing for patent term extensions and the ability to file pre-launch infringement suits to bolster pharmaceutical companies' financial incentives to create new and innovative products. *See generally* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

56. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches and ushering in an era of historic

revenues and profits for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1985, prescription drug revenue for brand and generic drugs totaled $21.6 billion; by 2013, total prescription drug revenue had climbed to more than $329.2 billion, with generic drugs accounting for 86% of prescriptions.[18] Generics are now dispensed 95% of the time when a generic form is available.[19]

57. The Hatch-Waxman Amendments simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. A manufacturer seeking approval to sell a generic version of a brand drug may instead file an ANDA. An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's NDA. The ANDA applicant must further show that the generic drug is bioequivalent (*i.e.*, that the active ingredient of the proposed generic drug is absorbed in the patient's blood stream to the same extent and for the same amount of time as the brand counterpart, 21 U.S.C.

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[18] *See* IMS INSTITUTE FOR HEALTHCARE INFORMATICS, MEDICINE USE AND SHIFTING COSTS OF HEALTHCARE, at 30, 51 (Apr. 2014), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/IMS-Medicine%20use%20and%20shifting%20cost%20of%20healthcare.pdf; Congressional Budget Office, *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 4 (July 1998).

[19] *Id.* at 51.

§ 355(j)(8)(B)), and that it is pharmaceutically equivalent (*e.g.*, that it contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug). Generic drugs that are both bioequivalent and pharmaceutically equivalent are considered "therapeutically equivalent" to the brand drug. *See generally* 21 U.S.C. §355(j) *et seq*.

58. The FDCA and Hatch-Waxman Amendments operate on the proven scientific principle that therapeutically equivalent drugs are substitutable. Generic drugs that are therapeutically equivalent to their brand counterparts are given an "AB" rating by the FDA, a designation which causes a pharmacy presented with a prescription for the brand to automatically dispense the generic instead.

2. Paragraph IV Certifications

59. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

a. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

b. that the patent for the brand drug has expired (a "Paragraph II certification");

c. that the patent for the brand drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

d. that the patent for the brand drug is invalid, unenforceable, and/or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

21 U.S.C. § 355(j)(2)(A)(vii).

60. To obtain FDA approval of an ANDA prior to the expiration of a patent or patents listed in the Orange Book, a generic manufacturer must file a Paragraph IV certification and serve timely notice to the brand manufacturer. The filing of an ANDA with a Paragraph IV certification gives rise to a cause of action for patent infringement pursuant to 35 U.S.C. § 271(e)(2) (if the patent holder can otherwise satisfy Rule 11). If the brand manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notice of the Paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of thirty months (the "30-month stay"), or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). The FDA may grant tentative approval to an ANDA when it determines that the ANDA would otherwise be ready for final approval but for the existence of an unexpired patent for which the generic filer has submitted a Paragraph III certification (*i.e.*, that the generic does not intend to market the ANDA product prior to the expiration of the patent) or the existence of a regulatory exclusivity, such as the 30-month stay.

3. First-Filer's 180-Day Exclusivity Period

61. Generics may be classified as (1) first-filer generics, (2) later-filing generics, or (3) the brand's own authorized generic.

62. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first generic manufacturer who files an ANDA with a Paragraph IV certification (the "first-filer") a 180-day period to market the generic version of the drug, during which the FDA may not grant final approval to any other later-filing generic manufacturer's ANDA for the same brand drug. 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. § 355(j)(5)(D). That is, when a first-filer files a substantially complete ANDA with the FDA and certifies that at least one unexpired patent listed in the Orange Book as covering the brand product is either invalid, unenforceable, or not infringed by the generic's product, the FDA cannot approve a later-filing generic company's ANDA until that first-filer generic has been on the market for 180 days, or until the first-filer's 180-day exclusivity has been forfeited. The 180-day window is referred to as the first-filer's 180-day "exclusivity" or "exclusivity period."

63. By contrast, a first-filer that informs the FDA that it intends to wait until all Orange Book listed patents expire before marketing its product (*e.g.*, one that files a Paragraph III certification as to all Orange Book-listed patents) will not receive a 180-day exclusivity period. Congress created the 180-day exclusivity period to incentivize generic manufacturers to file Paragraph IV certifications challenging weak patents, or to invent around such patents by creating non-infringing generics.

64. The Supreme Court has recognized that "this 180-day period of exclusivity can prove valuable, possibly worth several hundred million dollars" to the first-filer.[20]

65. An authorized generic, or AG, is simply the brand product, sold or licensed by the brand for sale, under generic trade dress, at a cheaper price than the brand price. Because the AG is already approved under the brand manufacturer's NDA, it can be marketed at any time, including during the first-filer's 180-day exclusivity period.[21]

66. A brand can also license a first-filer generic competitor to launch an authorized generic. The first-filer's launch of an authorized generic triggers its 180-day exclusivity period.

67. If the only versions of a drug on the market are the brand and the first-filer's generic product, then the first-filer prices its product below the brand product, but above what it would if there was more than one generic (such as an authorized

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[20] *FTC v. Actavis, Inc.*, 570 U.S. 136, 133 S. Ct. 2223, 2229 (2013) (internal citation and quotation marks omitted).

[21] *See, e.g.*, FDA, *Guidance for Industry, 180-Day Exclusivity: Questions and Answers*, at 13 (Jan. 2017), https://www.fda.gov/media/102650/download; ANDA Approval Letter from Carol Holquist, Deputy Director, Office of Regulatory Operations, FDA, to Meredith Selby, Senior Director, Regulatory Affairs, Par Pharmaceutical Inc., at 2 (May 9, 2017), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/090482Orig1s000ltr.pdf.

generic). The lack of competition from an authorized generic therefore inflates the price of a first-filer generic.

B. The Competitive Benefits of AB-Rated Generic Competition

68. Since the FDA deems AB-rated generic versions of brand drugs to be just as safe and effective as their brand counterparts, the only material mode of differentiating the two is their price. On average, generics are at least 10% less expensive than their brand counterparts when there is a single generic competitor. This discount typically increases to 50% - 80% (or more) when there are multiple generic competitors on the market for a given brand.

69. Every state has adopted laws that either require or permit pharmacies to automatically substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician has affirmatively requested the brand). Accordingly, once one generic equivalent enters the market, the generic quickly captures sales of the corresponding brand drug, often capturing 80% or more of the brand's sales within the first six months.

70. By 12 months post-generic entry, the Federal Trade Commission ("FTC") found that on average, generics had captured 90% of corresponding brand drug sales and (with multiple generics on the market) prices had dropped 85%

relative to brand prices.[22] That is because, once multiple generic competitors enter, the competitive process accelerates and multiple generic sellers typically compete vigorously with each other for market share by driving prices further down toward marginal manufacturing costs.[23] As a result, competition from generic drugs is viewed by brand drug companies, such as AstraZeneca, as a grave financial threat.

71. By contrast, generic competition enables purchasers (like Class members here) to purchase substantially cheaper generic versions of a drug instead of the more expensive brand, and to purchase generic versions of a drug at increasingly lower prices as more generic versions of that brand drug enter the market. In addition, generic competition enables purchasers to pay lower prices for their remaining brand companies when the brand company lowers its brand price to compete with the generic for sales.

72. Once exclusivity is lost and generic entry occurs – an event sometimes referred to as the "patent cliff" – the brand manufacturer can expect a significant

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[22] *See* FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS AT 8 (Jan. 2010) ("FTC Pay-for-Delay Study"), http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

[23] *See*, *e.g.*, Patricia M. Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, 43 J.L. & ECON. 311, 314, 339-41, 354-55 (Oct. 2000); R. Frank, *The Ongoing Regulation of Generic Drugs*, NEW ENG. J. MED., v. 357, pp. 1993-96 & n.20 (Nov. 2007).

drop in profits, as it is forced to either compete by dramatically lowering prices, or accept dramatically lower sales. The tradeoff of longer exclusivity rights in return for quick and effective generic entry after loss of exclusivity was fundamental to the policies and procedures that Congress established in the Hatch-Waxman Act, and embraced by the states in their generic substitution laws. "According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Billions more are saved when hospitals use generics."[24]

C. Brand and Generic Companies Have Strong Financial Incentives to Agree to Anticompetitive Terms

73. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices. Brand manufacturers, such as AstraZeneca, are well aware of generics' rapid erosion of their brand sales, and thus seek to delay and stall the impact of generic competition for as long as possible, sometimes (as here) resorting to illegal means.

74. One way that brand manufacturers game the system to anticompetitive effect is by paying generic manufacturers to delay entering the market. These

[24] *Generic Drugs Undergo Rigorous FDA Scrutiny*, FDA (Oct. 8, 2014), https://www.fda.gov/consumers/consumer-updates/generic-drugs-undergo-rigorous-fda-scrutiny.

agreements not to compete are sometimes referred to as "reverse payment agreements," "exclusion payment agreements," or "pay-for-delay agreements," which have long concerned the FTC. Brand and generic manufacturers execute exclusion payment agreements to take advantage of the regulatory consequences associated with the generic manufacturers' Paragraph IV certifications.

75. In a typical exclusion payment agreement, the brand manufacturer pays a generic manufacturer to delay or abandon market entry. The brand manufacturer preserves its monopoly by effectively paying some of its monopoly profits to the generic manufacturer, which in turn agrees to delay marketing its product.

76. One method of payment to a first-filer generic company comes in the form of the brand company's promise to not launch an "authorized generic" version of the brand drug during the first-filer's 180-day exclusivity. As discussed above, an authorized generic is the brand drug, sold under the brand NDA, but sold by the brand or a licensee under generic trade dress. Because the brand manufacturer already has approval to sell its brand drug, it does not need to file an ANDA or obtain any additional approval to market an authorized generic. Multiple courts have recognized that ANDA filers have no right to be free from competition from an authorized generic.

77. In a 2011 report issued at the request of Congress, the FTC concluded that no-authorized-generic promises were being used as a payment by brands to

generics for delayed generic entry, noting that "there is strong evidence that agreements not to compete with an authorized generic have become a way for brand-name companies to compensate generic competitors for delaying entry."[25]

78. For the brand company, an authorized generic launched during the first-filer's 180-day exclusivity (or longer) provides a low-cost, low-risk means to regain some of the revenue lost from the patent-cliff. However, an authorized generic launch has a huge negative impact on the first-filer's revenue. A first-filer generally earns about 80% of its total income from a given generic product during its exclusivity period. An authorized generic, when launched during that time, will capture 50% or more of total generic unit sales during that period,[26] and will cause generic prices to decrease as a result of the price competition.[27] A brand company's promise not to launch an authorized generic during the first-filer's 180-day

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[25] FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT ("FTC, Authorized Generic Drugs") (August 2011) at vi, https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf.

[26] *Id.* at iii, vi, 41-48, 57-59.

[27] *Id.* at, *e.g.*, ii-iii, vi-vii, 40, 5 n.21 (citing IMS CONSULTING, IMS HEALTH, ASSESSMENT OF AUTHORIZED GENERICS IN THE U.S. (2006) (written for PhRMA (Pharmaceutical Research and Manufacturers of America)), http://replay.web.archive.org/20061009134405/http://www.phrma.org/files/IMS%20Authorized%20Generics%20Report_6-22-06.pdf.

exclusivity period is thus a very valuable payment to the first-filer, doubling the first-filer's unit sales and more than doubling its revenues and profits (by removing a source of price competition). Correspondingly, a brand company's promise not to launch an authorized generic represents a substantial sacrifice of the revenues and profits for the brand that the brand company would have otherwise earned by launching an authorized generic. Those revenues and profits are instead ceded, by way of the no-authorized generic promise, to the first-filer generic, who has no right to be free from competition from an authorized generic.

79. For a first-filer preparing to market a generic version of a brand product like Seroquel XR, like Handa/Par for the 50mg, 150mg, 200mg and 300mg strengths and Accord for the 400mg strength, the difference between (1) selling the only generic product for six months and (2) selling a generic product while competing against an authorized generic for the first six months of generic marketing, is substantial, and worth up to hundreds of millions of dollars. These economic realities are well known in the pharmaceutical industry, and the FTC's authorized generic report cites numerous documents from industry participants confirming the financial impact of an authorized generic and, by necessary implication, its absence.

80. A no-authorized generic agreement between brand and generic drug companies – horizontal competitors – unjustly enriches both companies and injures consumers twice over: first, it prolongs the period during which only the high-priced

brand is available; and second, it ensures that, even after delayed generic competition begins, generic prices are artificially inflated by the absence of a second generic competitor (the authorized generic).

81. Here, Handa/Par and Accord each agreed to delay competing in the market for Seroquel XR in exchange for AstraZeneca's promise to Handa/Par and to Accord not to launch authorized generic Seroquel XR in competition with Handa/Par's and Accord's generic Seroquel XR products during Handa/Par's and Accord's respective 180-day exclusivity periods. As set forth further below, these promises not to launch authorized generic Seroquel XR, which were part of the Non-Compete Agreements, constituted large payments to each of Handa/Par and Accord for which there can be no redeeming procompetitive justification, because they represent *per se* illegal market allocation or output restriction agreements, and/or because even if analyzed under the rule of reason, a no-authorized-generic promise lacks any cognizable procompetitive justification as a matter of law.

D. Regulatory Impact of Pay-for-Delay Agreements on Final Approval

82. Generic companies that receive payments to delay the market entry of their generics for a period of years have no regulatory or economic incentive to seek final approval for their ANDAs until much closer in time to the agreed-upon, purchased launch date. Their resources are better spent on other ANDAs that have more immediate launch potentials and it is not in their best interest to obtain final

approval yet not launch in the near term, as it tends to raise anticompetitive red flags. The same is also true concerning the generics' manufacturing of commercial quantities of generic product intended for launch. Given the limited expiration shelf-life of generic drugs – which is usually 24 months – generic companies have no incentive to obtain ingredients and manufacture commercial quantities of product too far ahead of agreed-upon launch dates. It is also not unusual for generic companies that have entered into pay-for-delay agreements with brand companies to use the interim period of time between the agreement and the delayed entry date to make adjustments to certain aspects of their ANDA that would otherwise not be made or would ordinarily be made post-approval and post-commercial launch.

83. It is also often the case that FDA is made aware of Paragraph IV patent litigation settlements between brand and generic companies, as well as the agreed upon entry date. Given the limited resources of FDA, it has no interest in working to grant immediate final approval to ANDAs for generic drugs that are not slated, because of an agreement between the generic and brand companies, to enter the market for several years. Most often, and regardless of its knowledge or lack of knowledge about patent litigation settlements, FDA will simply wait, or even require that generic companies initiate additional, final approval activities nearer in time to the date that the generics know they are eligible or desire to enter the market with their ANDA-based products.

84. In the context of the facts at issue here, after settling with AstraZeneca in 2011 with a generic entry date years ahead in exchange for a reverse payment, Handa (and eventually Par), and Accord had no interest in obtaining, and no need to obtain, final approval of their respective generic Seroquel XR ANDAs in the near term, and the FDA, likewise, had no interest or need to grant such final approval until the agreed generic launch date was nearing.

85. As concerns Accord, the agreement between AstraZeneca and Accord delayed the launch of Accord's generic Seroquel XR 400 mg ANDA product until November 1, 2016. Thus, Accord and FDA geared their respective resources towards meeting that date in 2016, not an earlier period of time. Indeed, Accord's 400 mg generic Seroquel XR ANDA received final approval precisely on November 1, 2016, at which time it entered the market. The timing of final FDA approval was no coincidence, but a direct result of the agreed entry date that AstraZeneca had purchased with its large reverse payment to Accord.

86. As concerns Handa (and Par), AstraZeneca and Handa/Par delayed the launch of Handa's generic Seroquel XR 50, 150, 200 and 300 mg products until November 1, 2016, and Handa/Par had the additional contractual right and economic incentive to launch and sell generic product as supplied to it by AstraZeneca for at least 180 days at least in part because Handa/Par could avoid manufacturing responsibilities and costs by distributing product supplied by AstraZeneca. Thus,

Handa (and Par) had no incentive to seek final approval for its ANDA versions of these milligram strengths until approximately 180 days after November 1, 2016. Handa (and eventually Par) and FDA geared their respective resources towards final approval of their ANDA-based products for May 2017. Par launched less expensive generic versions of 50, 150, 200 and 300 mg Seroquel XR on November 1, 2016 with product as supplied by AstraZeneca, and thereafter obtained final ANDA approval from FDA for those same milligram strengths in early May 2017. Again, this sequence of events was no coincidence, but a direct result of the agreed entry date that AstraZeneca had purchased with its large reverse payment to Handa.

E. Pay-for-Delay Agreements with First-Filers Can Create Bottlenecks for Later-Filing Generics

87. An anticompetitive agreement entered into between the brand and the first-filer generic often creates a bottleneck preventing the later ANDA filers from launching, since the later ANDA filers cannot launch earlier than 180 days after the first-filer's launch.

88. Later ANDA filers have more modest financial prospects than the first-filer generic because the later filers have no expectation of any form of market exclusivity, such as the first-filer's 180-day exclusivity. By the time the later ANDA filers enter the market, they typically must compete with the brand, the first-filer, an authorized generic, and other later filers.

89. Nevertheless, in the absence of an anticompetitive agreement between the brand company and the first-filer, the later ANDA filers have procompetitive incentives. They are motivated to enter the market as early as possible because the sooner they enter, the sooner they can earn profits by competing for sales in the market, which results in lower prices.

90. However, later ANDA filers cannot obtain final FDA approval to enter the market until the first-filer's 180-day exclusivity has run or been forfeited. An agreement between the brand and the first-filer that delays the first-filer's entry thus creates a bottleneck that, by delaying the first filer's 180-day exclusivity, consequently delays the later ANDA filers' entry as well.

91. Agreements causing such bottlenecks are fundamentally anticompetitive and are contrary to the goals of the Hatch-Waxman statutory scheme. In particular, they extend the brand manufacturer's monopoly profits by blocking and delaying access to more affordable generic drugs, forcing purchasers to buy the more-expensive brand drug instead.

VI. FACTUAL ALLEGATIONS

A. AstraZeneca's Seroquel XR Patents

92. AstraZeneca Pharmaceuticals LP is the holder of NDA No. 22-047, under which the FDA granted approval for extended-release tablets containing various different dosage strengths of the active ingredient 11-[4-[2-(2-

hydroxyethoxy)ethyl]-1-piperazinyl] dibenzo [b,f] [1,4] thiazepine fumarate, which is commonly referred to as quetiapine fumarate. AstraZeneca Pharmaceuticals LP markets these tablets in the United States under the trademark Seroquel® XR.

93. AstraZeneca Pharmaceuticals LP is the owner of U.S. Patent No. 4,879,288 ("the '288 Patent"). The '288 Patent issued on November 7, 1989 from United States Application No. 07/028,473, which was filed on March 20, 1987. Although the '288 Patent was originally set to expire on March 20, 2007, it received a patent term extension ("PTE") of 1,651 days under 35 U.S.C. 156. Based upon the PTE, the '288 Patent expired on September 26, 2011.

94. AstraZeneca UK Limited is the owner of the '437 Patent. The '437 Patent issued on September 7, 1999 from United States Application No. 08/864,306, which was filed on May 28, 1997. The '437 Patent expired on May 28, 2017.

95. AstraZeneca submitted the '288 and '437 Patents for listing in the FDA Orange Book under NDA No. 22-047. AstraZeneca Pharmaceuticals LP received pediatric exclusivity[28] for NDA No. 22-047, and the pediatric exclusivity associated with the '288 and '437 Patents expired on March 26, 2012 and November 28, 2017, respectively.

[28] Congress enacted 35 U.S.C. § 355a to incentivize drug developers to conduct studies on their drugs in pediatric patients. Congress established as an incentive, that if the studies were successful, FDA would grant an additional 6-months of regulatory exclusivity running after patent expiration, during which the FDA would not approve generic versions of the studied drug.

96. Because the '288 Patent expired on September 26, 2011 and its pediatric exclusivity expired on March 26, 2012, neither the '288 Patent nor its associated pediatric exclusivity could have affected any generic drug company's right, ability or willingness to market a generic version of Seroquel XR after March 26, 2012.

97. The '437 Patent contains one independent claim and fourteen dependent claims. Independent claim 1 recites

> A sustained release formulation comprising a gelling agent and 11-[4-[2-(2-hydroxyethoxy) ethyl]-1-piperazinyl]dibenzo-[b,f][1,4]-thiazepine or a pharma-ceutically acceptable salt thereof, together with one or more pharmaceutically acceptable excipients.

Each of the fourteen dependent claims in the '437 Patent incorporate the requirements of claim 1, including the requirement for a "gelling agent." "It is axiomatic that dependent claims cannot be found infringed unless the claims from which they depend have been found to be infringed." *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989). Accordingly, no generic drug company's ANDA or generic drug product could infringe the '437 Patent unless it contained, *inter alia*, a "gelling agent" as claimed in the '437 Patent.

B. Handa and Accord File ANDAs for Generic Versions of Seroquel XR

98. Handa and Accord were the first generic manufacturers to file ANDAs with the FDA containing Paragraph IV certifications regarding Seroquel XR patents.

99. Handa filed ANDA No. 90-482 for a generic version of extended-release quetiapine fumarate, and amended it four times, between spring and fall of 2008. On information and belief, Handa was the first applicant to file a substantially complete application containing a Paragraph IV certification for the 50mg, 150mg, 200mg, 300mg strengths, making Handa eligible for 180 days of regulatory exclusivity for those strengths of generic Seroquel XR. Handa's ANDA also included a Paragraph IV certification for the 400mg strength, although Handa was not the first applicant to file a substantially complete application containing a Paragraph IV certification for the 400mg strength.

100. Accord filed ANDA No. 90-681 for a generic version of extended-release quetiapine fumarate on June 18, 2008.[29] On information and belief, Accord was the first applicant to file a substantially complete application containing a Paragraph IV certification for the 400mg strength of extended-release quetiapine fumarate, making Accord eligible for 180 days of regulatory exclusivity for that strength of generic Seroquel XR.

[29] *See* Final Approval Letter from Carol Holquist, Deputy Director, Office of Regulatory Operations, FDA, to Sabita Nair, Senior Director, Regulatory Affairs, Accord Healthcare Inc., at 2 (Nov. 1, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/090681Orig1s000TAltr.pdf; FDA, Paragraph IV Patent Certifications (Dec. 1, 2020), https://www.fda.gov/media/133240/download.

101. Because Handa and Accord were the first companies to file substantially complete ANDAs with Paragraph IV certifications, they each stood to receive a significant and potentially highly profitable benefit under 21 U.S.C. 355(j)(5)(B)(iv): 180 days of marketing exclusivity during which the FDA would not give final approval to any other ANDA filer's generic equivalent of Seroquel XR.

102. After receiving confirmation of receipt from the FDA for their ANDAs, Handa sent four separate Paragraph IV notice letters to AstraZeneca of its ANDA, each containing Paragraph IV certifications that included a detailed statement of the factual and legal basis as to why the '437 Patent was invalid, unenforceable, and/or not infringed by Handa's ANDA products. The Paragraph IV notice letters included certifications that Handa intended to seek final FDA approval to market and to launch its AB-rated generic Seroquel XR products before the expiration of the '437 patent. The Paragraph IV notice letters also included an offer of confidential access to Handa's ANDA as required under the Hatch-Waxman Act. The notice letters were dated July 10, 2008, July 23, 2008, October 16, 2008, and November 14, 2008. The notice letters gave rise to an artificial act of infringement for purposes of creating standing, thereby allowing AstraZeneca to bring a cause of action for infringement against Handa under the Hatch-Waxman Act (if AstraZeneca otherwise had a basis to sue under Rule 11).

103. Similarly, Accord sent AstraZeneca two separate Paragraph IV notice letters dated September 5, 2008 and January 23, 2009.[30] Accord's Paragraph IV certifications were required by statute to include "a detailed statement of the factual and legal basis of the opinion of the applicant that ['437 Patent] is invalid or will not be infringed," by Accord's generic Seroquel XR products.[31] The Paragraph IV notice letters included certifications that Accord intended to seek final FDA approval to market and to launch its AB-rated generic Seroquel XR products before the expiration of the '437 patent. On information and belief, Accord's Paragraph IV notice letters also included an offer of confidential access to Accord's ANDA as required under the Hatch-Waxman Act. The notice letters gave rise to an artificial act of infringement for purposes of creating standing, thereby allowing AstraZeneca to bring a cause of action for infringement against Accord under the Hatch-Waxman Act (if AstraZeneca otherwise had a basis to sue under Rule 11).

C. The Seroquel XR Patent Litigation

104. AstraZeneca filed three patent infringement lawsuits against Handa in response to Handa's Paragraph IV certification notice letters. First, in response to Handa's notice letters dated July 10, 2008 and July 23, 2008, AstraZeneca filed civil

[30] Stipulated Facts ¶ 27, ECF No. 156-1, *AstraZeneca Pharmaceuticals et al. v. Handa Pharmaceuticals LLC*, 3:10-cv-01835-JAP-TJB (D.N.J.).

[31] 21 U.S.C. § 355(j)(2)(B)(iv)(II).

action no. 08-cv-3773 in the District of New Jersey on July 28, 2008. Second, on October 28, 2008, AstraZeneca filed civil action no. 08-cv-5328 in the District of New Jersey in response to Handa's notice letter dated October 16, 2008. Third, on December 8, 2008, AstraZeneca filed civil action no. 08-cv-5997 in the District of New Jersey in response to Handa's notice letter dated November 14, 2008.

105. AstraZeneca filed two patent infringement lawsuits against Accord in response to Accord's Paragraph IV certification notice letters. First, on September 26, 2008, AstraZeneca filed civil action no. 08-cv-04804 against Accord in the District of New Jersey in response to Accord's notice letter dated September 5, 2008. Second, on February 10, 2009, AstraZeneca filed civil action no. 09-cv-00619 against Accord in the District of New Jersey in response to Accord's notice letter dated January 23, 2009.

106. Several generic drug companies in addition to Handa and Accord filed ANDAs seeking approval of generic versions of Seroquel XR ("the Later-Filing Generics"). AstraZeneca subsequently filed seven patent infringement lawsuits relating to generic Seroquel XR against four of the Later-Filing Generics in the District of New Jersey. On April 8, 2010, AstraZeneca filed civil action no. 10-cv-1835 against Anchen Pharmaceuticals, Inc. and Anchen, Inc. (together, "Anchen"). On August 16, 2010, AstraZeneca filed civil action no. 10-cv-4203 against Osmotica Pharmaceutical Corporation ("Osmotica"). Also on August 16, 2010, AstraZeneca

filed civil action no. 10-cv-4205 against Torrent Pharmaceuticals Limited and Torrent Pharma Inc. (together, "Torrent"). On September 28, 2010, AstraZeneca filed civil action no. 10-cv-4971 against Torrent. On October 22, 2010, AstraZeneca filed civil action no. 10-cv-5519 against Mylan Pharmaceuticals, Inc. and Mylan, Inc. (together, "Mylan"). On April 29, 2011, AstraZeneca filed civil action no. 11-cv-2483 against Mylan. Also on April 29, 2011, AstraZeneca filed civil action no. 11-cv-2484 against Osmotica. The foregoing seven patent infringement lawsuits are referred to herein as "the Later-Filer Seroquel XR Patent Litigation."

107. The Handa Seroquel XR Patent Litigation, the Accord Seroquel XR Patent Litigation, and the Later-Filer Seroquel XR Patent Litigation are referred to collectively as "the Seroquel XR Patent Litigation."

108. During claim construction proceedings in the Seroquel XR Patent Litigation, the district court construed the term "gelling agent" as "any substance which forms a gel when in contact with water."[32]

109. On information and belief, the 30-month stays preventing final FDA approval of Handa's ANDA expired at various dates in 2011, although Handa and AstraZeneca entered into a stipulation that Handa would not seek to enter the market

[32] *See AstraZeneca Pharm., LP v. Anchen Pharm., Inc.*, Civ. No. 10-cv-1835, 2012 WL 1065458, at *2 (D.N.J. Mar. 29, 2012).

prior to March 26, 2012. On information and belief, the 30-month stay preventing final FDA approval of Accord's ANDA also was set to expire in 2011.

110. On or about September 29, 2011, as further described below, AstraZeneca reached a settlement with Handa resolving the Handa Seroquel XR Patent Litigation. As a result, some or all of Handa's defenses in the Handa Seroquel XR Patent Litigation were never adjudicated.

111. On or about October 5, 2011, AstraZeneca reached a settlement with Accord resolving the Accord Seroquel XR Patent Litigation. As a result, on information and belief some or all of Accord's defenses in the Accord Seroquel XR Patent Litigation were never adjudicated.

112. AstraZeneca did not settle with the Later-Filing Generics prior to trial and the Later-Filer Seroquel XR Patent Litigation proceeded to a bench trial in October 2011. At the trial, three of the Later-Filing Generics – namely, Anchen, Osmotica, and Mylan – did not advance a non-infringement defense, in part because their generic version(s) of Seroquel XR used hydroxypropylmethylcellulose ("HPMC"), the "preferred gelling agent of the '437 patent":

> The proposed ANDA products of Anchen, Osmotica and Mylan Pharms contain HPMC, the preferred gelling agent of the '437 patent. Anchen, Mylan and Osmotica have not contested that their proposed ANDA products would infringe various claims of the '437 patent if those claims are not found to be invalid.[33]

[33] *See AstraZeneca Pharm., LP*, 2012 WL 1065458, at *8.

113. The generic Seroquel XR product of the fourth Later-Filing Generic – *i.e.*, Torrent – did not use HPMC but did use a "naturally-occurring hydrophilic polymer" sold under the brand name Viscarin 209 that "hydrates and swells in the presence of water."[34] The district court in the Later-Filer Seroquel XR Patent Litigation concluded that Viscarin 209 was indeed a "gelling agent" under the court's claim construction, and found that Torrent's generic Seroquel XR product infringed the '437 Patent.[35]

D. Handa's Unadjudicated Defenses Were Meritorious

114. Unlike the Later-Filing Generics, Handa successfully designed around the '437 Patent by developing a non-infringing product that did not contain as "gelling agent" as required by each of the claims of the '437 Patent. Instead of using a hydrophilic "gelling agent," Handa's products used a hydrophobic compound known as hydrogenated vegetable oil ("HVO"). Each of the Later-Filing Generics, in contrast, used hydrophilic compounds that formed gels when placed in contact with water. As explained below, Handa obtained a patent on its novel formulation despite the '437 Patent, reflecting the determination of the United States Patent and Trademark Office ("PTO") that Handa's formulation was patentably distinct from the formulation claimed in the '437 Patent.

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[34] *Id*. at *11.

[35] *Id*. at *13.

115. On July 24, 2008, Handa filed United States Provisional Application No. 61/083,270 ("the '270 Application"). On September 5, 2008, Handa filed United States Application Serial No. 12/205,356 ("the '356 Application"), which claimed the benefit of the filing date of the '270 Application. On May 8, 2012, the '356 Application issued as United States Patent No. 8,173,637 ("the Handa '637A Patent"). On March 28, 2011, Handa filed United States Application Serial No. 13/073,873 ("the '873 Application"), which claimed the benefit of the filing date of the '356 and '270 Applications. On August 23, 2011, the '873 Application issued as United States Patent No. 8,003,637 ("the Handa '637B Patent").

116. Handa disclosed the '288 and '437 Patents as prior art in the applications that led to the Handa '637A Patent and Handa '637B Patent. By issuing the Handa '637A Patent and Handa '637B Patent despite AstraZeneca's '288 and '479 Patents, the examiner necessarily determined that the claimed compositions in the Handa '637A Patent and in the Handa '637B Patent were patentably distinct from the compositions disclosed and claimed in AstraZeneca's '288 and '479 Patents.

117. As Handa's own patents explain, HVO is a "hydrophobic" material that is "non-gelling":

> Examples of ***hydrophobic*** materials that can be used to form a ***non-gelling*** or non-swelling controlled release matrix for the atypical antipsychotic drug include beeswax, white wax, emulsifying wax, ***hydrogenated vegetable oil***, hydrogenated castor oil, microcrystalline wax, cetyl alcohol, stearyl alcohol, free wax acids such as stearic acid, esters of wax acids, propylene glycol mono stearate, glycerol mono

> stearate, carnauba wax, palm wax, candelilla wax, lignite wax, ozokerite, ceresin wax, lardaceine, China wax and mixtures thereof. Other possible rate controlling excipients useful in the present invention include saturated hydrocarbons having from 25 to 31 carbon atoms, saturated alcohols having from 25 to 31 carbon atoms, saturated monocarboxylic acids having from 25 to 31 carbon atoms, esters obtained from said alcohols and monocarboxylic acids which are described in U.S. Pat. No. 6,923,984, incorporated herein by reference.[36]

118. The district court's claim construction in the Seroquel XR Patent Litigation requires that, *inter alia*, the "gelling agent" interact with "water" to "form[] a gel" (*see supra*); accordingly, one of the important characteristics in determining whether a particular compound is a "gelling agent" is whether it is "hydrophilic" (*i.e.*, water loving) or "hydrophobic" (*i.e.*, water hating). This is so because "hydrophobic" compounds such as HVO generally do not interact with water. Indeed, the '437 Patent itself indicates that the claimed "gelling agent" must be "hydrophilic": "The term gelling agent as used herein means any substance, ***particularly a hydrophilic substance***, which forms a gel when in contact with water. . . ."[37]

119. Although Handa settled before trial in the Seroquel XR Patent Litigation, evidence and arguments at the trial for the non-settling generics confirm that Handa's non-infringement defense would have prevailed at trial. In opening

[36] '637A Patent at 6:24-39 (emphasis added).

[37] '437 Patent at 2:43-45 (emphasis added).

arguments, AstraZeneca's counsel focused on the fact that the Viscarin 209 in Torrent's product was "hydrophilic" and interacts substantially with water:

> Torrent does not use HPMC. Instead, Torrent uses a commercial carrageenan material called Viscarin GP209. Carrageenan, by way of background, is a naturally-occurring polymer, harvested from, believe it or not, seaweed, like FMC's Viscarin GP209 product is a hydrophilic, that is it's water loving, it hydrates and swells in the presence of the water.[38]

120. During the questioning of AstraZeneca's expert regarding Viscarin 209, the hydrophilicity of the compound was a focal point of the examination:

> Q. Can you explain what part of the '437 patent informs you what is contemplated by the word "gel"?
>
> A. Go back to the patent.
>
> Q. I believe it's tab four.
>
> A. Tab four. In the second column is yellow highlighted materials of the term "gelling agent" as used herein means a substance particularly a hydrophilic substance, which forms a gel when in contact with water and thus, includes such substances as, and it gives a long list of substances which are polymers. The gelling agent is preferably hydroxypropylmethylcellulose.
>
> Q. The patent states it's particularly a hydrophilic substance. Can you explain to the Court what a hydrophilic gelling agent is?
>
> A. Hydrophilic comes from hydro, water and philic, loves so it's a material that likes water, has intrinsic positive interaction with water, will tend to hydrate and swell.
>
> Q. So hydrophilic gelling agents will hydrate and swell?

[38] Later-Filer Seroquel XR Patent Litigation Trial Transcript (Oct. 3, 2011) at 8.

A. They will hydrate and swell. . . .

Q. Now, Dr. Prud'homme, a moment ago when we were looking at the '437 patent, we saw it refers to the use of hydrophilic polymers as gelling agents.

Q. Are carrageenans [*i.e.*, the compounds in Viscarin 209] hydrophilic polymers?

A. Yes, they are.

Q. And what happens to these hydrophilic carrageenan polymers when they come in contact with water?

A. Well, they will tend to hydrate and swell. They also tend to gel.[39]

This questioning, like the text in the '437 Patent itself and AstraZeneca's opening argument, highlight why a hydrophobic compound like the HVO in Handa's products was very unlikely to be found to be a "gelling agent" as required by the claims of the '437 Patent. Furthermore, HVO could not have satisfied the requirement for a "gelling agent" under the doctrine of equivalents because HVO is substantially different from the claimed "gelling agent" and further does not satisfy the doctrine of equivalents's function-way-result test.

121. Had Handa not settled with AstraZeneca, Handa would have prevailed on its non-infringement defense. In addition, on information and belief, Handa had other meritorious defenses.

[39] *Id*. (Oct. 3, 2011) at 74:7-79:25.

E. AstraZeneca Enters into Unlawful Reverse-Payment Agreements with Handa and Accord

122. On or about September 29, 2011, AstraZeneca and Handa entered into the Handa Non-Compete Agreement.[40] On or about October 5, 2011, AstraZeneca and Accord entered into the Accord Non-Compete Agreement.[41]

123. Under the terms of the Non-Compete Agreements, Handa and Accord respectively agreed to quit their patent fights and delay their respective generic Seroquel XR launches until November 1, 2016. In exchange for Handa's and Accord's agreements to delay launching, AstraZeneca agreed not to compete with Handa or Accord by launching an authorized generic for the first six months after their launches, *i.e.*, AstraZeneca agreed not to launch an authorized generic until May 1, 2017. The purpose and effect of the Non-Compete Agreements was to prevent AstraZeneca from facing lower-priced generic competition for up to five

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[40] *See US District Court Finds SEROQUEL XR Formulation Patent Valid and Infringed*, https://www.businesswire.com/news/home/20120329006628/en/District-Court-Finds-SEROQUEL-XR-Formulation-Patent (Mar. 29, 2012) ("On September 29, 2011, AstraZeneca granted Handa a license to the 5,948,437 patent effective November 1, 2016, or earlier under certain circumstances.").

[41] *See AstraZeneca enters into a settlement agreement with Accord Healthcare, Inc. and Intas Pharmaceuticals Ltd regarding US SEROQUEL XR® patent litigation* (Oct. 5, 2011), https://www.astrazeneca.com/media-centre/press-releases/2011/AstraZeneca-enters-into-a-settlement-agreement-with-Accord-Healthcare-Inc-and-Intas-Pharmaceuticals-Ltd-regarding-US-SEROQUEL-XR-patent-litigation-05102011.html#modal-historic-confirmation.

years and to allow Handa and Accord to sell generic Seroquel XR without competition from authorized generic Seroquel XR for six months after Handa's and Accord's November 1, 2016 generic Seroquel launches, from November 1, 2016 through April 30, 2017.

124. On October 29, 2012, Par announced that it had acquired Handa's ANDA No. 90-482. As part of Par's acquisition of Handa's ANDA, Handa assigned the Handa Non-Compete Agreement to Par.[42] A press release issued by Handa on May 10, 2017 stated that, under its agreement with Par, "Par's Quetiapine XR ANDA was developed by Handa and acquired by Par on August 3, 2012. Handa retains the right to a portion of its profits from the sale of the product, pursuant to its agreement with Par." As a result of these transactions, Par became an active participant and co-conspirator in the pre-existing conspiracy between Handa and AstraZeneca and is jointly and severally liable for all harm flowing from the conspiracy.

125. AstraZeneca always intended to launch an authorized generic to compete with Handa/Par's and Accord's generic Seroquel XR products, as evident from the fact that AstraZeneca actually did so on the first day it was allowed to under

[42] *See Par Pharmaceutical Acquires Rights to Market and Distribute Generic Seroquel XR® in the U.S.* (Oct. 29, 2012), https://www.prnewswire.com/news-releases/par-pharmaceutical-acquires-rights-to-market-and-distribute-generic-seroquel-xr-in-the-us-176239031.html.

the terms of the Non-Compete Agreements.[43] But for the Non-Compete Agreements, AstraZeneca would have launched authorized generic Seroquel XR at the time that Handa/Par and Accord launched, and competed for generic Seroquel XR sales during Handa/Par's and Accord's 180-day exclusivity periods. Instead, because of the Non-Compete Agreements, AstraZeneca waited 180 days after Handa/Par's and Accord's generic Seroquel XR launches to launch competitive authorized generic Seroquel XR.

126. Accord received FDA tentative approval for its ANDA No. 90-0681 on December 14, 2010 and final approval on November 1, 2016.[44] On information and belief, Accord's 400mg generic Seroquel XR product would have received final approval before November 1, 2016 absent the Accord Non-Compete Agreement. Handa received tentative approval from FDA on December 9, 2010.[45] Par obtained final FDA approval for ANDA No. 90-482 on May 9, 2017, almost exactly the end

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[43] DailyMed, LABEL: QUETIAPINE FUMARATE EXTENDED RELEASE, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7283b14f-023d-466f-a7eb-4356803d7c65&audience=consumer (showing AstraZeneca with a May 1, 2017 launch date as an "NDA Authorized Generic").

[44] *See* Final Approval Letter from Carol Holquist to Sabita Nair, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/090681Orig1s000TAltr.pdf.

[45] *See* Tentative Approval Letter from Keith Webber to Maggie Chang at 1, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/090482s000ltr.pdf .

of its 180-day exclusivity period.[46] On information and belief, absent the Handa Non-Compete Agreement, Handa/Par's 50mg, 150mg, 200mg and 300mg strengths of generic Seroquel XR would have received final FDA approval before November 1, 2016. Handa's and Accord's tentative FDA approvals meant that their ANDAs were ready for FDA final approval but for the existence of a patent or regulatory barrier.

127. On information and belief, AstraZeneca provided Handa/Par and Accord with licenses under its '437 Patent, and reverse payments in the form of agreements not to launch authorized generic versions of Handa/Par's and Accord's respective strengths of generic Seroquel XR ("no-AG provisions" or "no-AG promises"). AstraZeneca was motivated to make these reverse payments because it was a preferable alternative to AstraZeneca than risking an adverse ruling on its patent, which would have caused earlier generic Seroquel XR entry.

128. But-for the Non-Compete Agreements, Par/Handa and Accord would have been ready, able, and willing to launch their respective strengths of generic Seroquel XR much earlier. Handa/Par's and Accord's generic Seroquel XR products would have received final approval from FDA upon (1) the conclusion of the 30-

[46] *Handa Pharmaceuticals, Inc. Announces FDA Approval for Generic Version of AstraZeneca's SEROQUEL XR® Extended Release Tablets* (May 10, 2017), https://handapharma.com/handa-pharmaceuticals-inc-announces-fda-approval-for-generic-version-of-astrazenecas-seroquel-xr-extended-release-tablets/.

month stays (or upon termination of the stipulation to delay marketing until March 27, 2012); (2) litigation victory by Handa/Par and Accord earlier than November 1, 2016; or (3) a licensed generic Seroquel XR entry date earlier than November 1, 2016 pursuant to agreement(s) with AstraZeneca that did not include unlawful reverse payments from AstraZeneca to induce delay. *See, e.g.*, *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 405 (3d Cir. 2015) ("when the parties' settlement includes a [payment], the generic also presumably agrees to an early entry date that is later than it would have otherwise accepted."); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d at 751-52 (a reverse payment "is likely to induce the generic to agree to enter the market at a date later than that to which it would otherwise agree").

129. By on or about September 29, 2011, when the Handa Non-Compete Agreement was executed, Seroquel XR was generating nearly a billion dollars per year in revenues for AstraZeneca. Losing a substantial portion of that revenue stream in the event Handa and/or Accord were to prevail on non-infringement or other defenses – or in the event that AstraZeneca had not induced Handa and/or Accord with reverse payments to agree to delay launching generic Seroquel XR for 5 years – would have drastically reduced AstraZeneca's profits. Thus, AstraZeneca had enormous incentives to avoid competition from Handa and Accord by entering into the Non-Compete Agreements.

130. AstraZeneca's waiting to launch authorized generic Seroquel XR until Handa/Par's and Accord's 180-day exclusivities expired did not make economic sense. It would have been more lucrative for AstraZeneca to have simply launched authorized generic Seroquel XR immediately upon Handa/Par's and Accord's launches. AstraZeneca only agreed to delay its authorized generic launch until May 1, 2017, 180 days after Handa/Par and Accord launched generic Seroquel XR, as a *quid pro quo* for Handa/Par's and Accord's respective agreements to delay generic Seroquel XR competition until November 1, 2016. As explained below, Plaintiffs were not on notice of AstraZeneca's large reverse payments to Handa/Par and to Accord until at least the time when it became clear that AstraZeneca took the plainly irrational path of delaying its corresponding authorized generic Seroquel XR launch.

131. On information and belief, as consideration for Handa/Par's and Accord's agreement to forgo selling generic extended-release quetiapine fumarate in competition with AstraZeneca's branded Seroquel XR for up to five years, AstraZeneca agreed to share with Handa/Par and Accord the monopoly profits from sales of branded Seroquel XR in the form of covenants not to compete with Handa/Par's and Accord's generics with authorized generic Seroquel XR. Instead of competing, which would have resulted in lower prices of both generic and branded Seroquel XR, AstraZeneca agreed and conspired with Handa/Par and with Accord

to maintain the prices of extended-release quetiapine fumarate at supracompetitive levels.

132. The Non-Compete Agreements benefitted Handa/Par and Accord by guaranteeing that they would be the sole generic seller on the market for their respective strengths during their 180-day exclusivity periods, which significantly increased Handa/Par's and Accord's anticipated sales revenues during their exclusivity periods because: (1) Handa/Par and Accord would capture all of the sales that would otherwise have gone to competing authorized generic Seroquel XR, and (2) Handa/Par and Accord would be able to charge significantly higher prices for their generic Seroquel XR products without price competition from competing authorized generic Seroquel XR.

133. A brand company's launch of a competing authorized generic is extremely costly to any first-filer generic, such as Handa/Par and Accord, because the authorized generic erodes the first-filer's share of the overall generic volume *and* pushes down generic prices. The authorized generic also cuts into the first-filer's long-term "first mover advantage," *i.e.*, the continuing market advantage that can accrue to the first entrant.[47] As the FTC noted in a June 2009 report on authorized generics, "consumers benefit and the healthcare system saves money during the 180-day exclusivity period when an [authorized generic] enters the market, due to the

[47] *See* FTC, Authorized Generic Drugs at 93.

greater discounting that accompanies the added competition provided by the [authorized generic]."[48] Thus, AstraZeneca's covenants not to launch authorized generic Seroquel XR during Handa/Par's and Accord's exclusivity periods were extremely valuable to Handa/Par and Accord.

134. Relatedly, AstraZeneca sacrificed large profits through its agreements not to launch authorized generics of Handa/Par's and Accord's respective strengths of generic Seroquel XR. Absent the unlawful Non-Compete Agreements, it would make economic sense for AstraZeneca to launch authorized generics during Handa/Par's and Accord's 180-day marketing exclusivity periods so that AstraZeneca would retain 50% of the sales that Handa/Par's and Accord's less expensive generics otherwise would otherwise capture.

135. As alleged above, an authorized generic typically captures approximately 50% of the generic unit sales during the first 180 days of generic marketing. Thus, AstraZeneca's promise to not launch an authorized generic Seroquel XR (the no-AG provision) constituted very large payments to Handa/Par and Accord.

136. Specifically, U.S. sales of Seroquel XR for the four dosage strengths for which Par was the first-filer (the 50mg, 150mg, 200mg and 300mg strengths) were, and were expected to be, approximately $911 million for the 12 months ending

[48] *Id.* at ii.

September 30, 2016.[49] Thus Defendants could assume that 6 months (or half a year) of brand sales (the duration of AstraZeneca's covenant not to launch an authorized generic) would generate revenue of approximately $455.5 million (half of AstraZeneca's $911 million in annual Seroquel XR revenue).

137. As is common in the pharmaceutical industry, the generic is expected to take 80% (or more) of the brand sales over the first six months following generic entry. Thus, approximately $364.4 million worth of brand sales would be converted to the generic ($455.5 million * 0.8) during the period of Handa/Par's 180-day exclusivity (the duration of AstraZeneca's covenant not to launch an authorized generic). As is also common, with only one generic on the market, the generic is typically priced at 90% of the brand, which would result in generic sales of approximately $327.96 million ($364.4 million * 0.9). Thus, the generic Seroquel XR sales revenue that would have reasonably been anticipated by Handa/Par during the 180-day exclusivity period without competition from an AG would be approximately $327.96 million.

138. Handa/Par's expectations would have differed dramatically if AstraZeneca had not promised to refrain from competing with authorized generic

[49] Handa Pharmaceuticals Announces Endo Begins Shipping Generic Version of AstraZeneca's SEROQUEL XR® (Nov. 1, 2016), https://handapharma.com/handa-pharmaceuticals-announces-endo-begins-shipping-generic-version-of-astrazenecas-seroquel-xr/.

Seroquel XR. According to an FDA study of the effects of additional generic competitors on the generic price, the entry of a second generic drives the average generic price down to 52% of the brand price.[50] Thus, while the generics would still take 80% of six months of brand sales, or $364.4 million, the generic sales value would drop to $189.488 million ($364.4 million * 0.52). And, it would reasonably be expected that those sales would be split evenly (50% / 50%) between Handa/Par and AstraZeneca's authorized generic.[51] Thus, without the no-AG promise in the Handa Non-Compete Agreement, Handa/Par's sales of generic Seroquel XR during the first 6 months would be expected to be approximately $94.744 million ($189.488 million * 0.5).

139. As a result, the expected value at the time of the Handa Non-Compete Agreement to Handa/Par of the no-AG provision versus facing competition from an AG would have been as much as approximately $233.216 million, the difference between the amount Handa/Par would reasonably expect to earn as the only generic seller on the market for 180 days following launch and the amount it would

[50] FDA, Generic Competition and Drug Prices (current as of Dec. 3, 2020), https://www.fda.gov/about-fda/center-drug-evaluation-and-research/generic-competition-and-drug-prices.

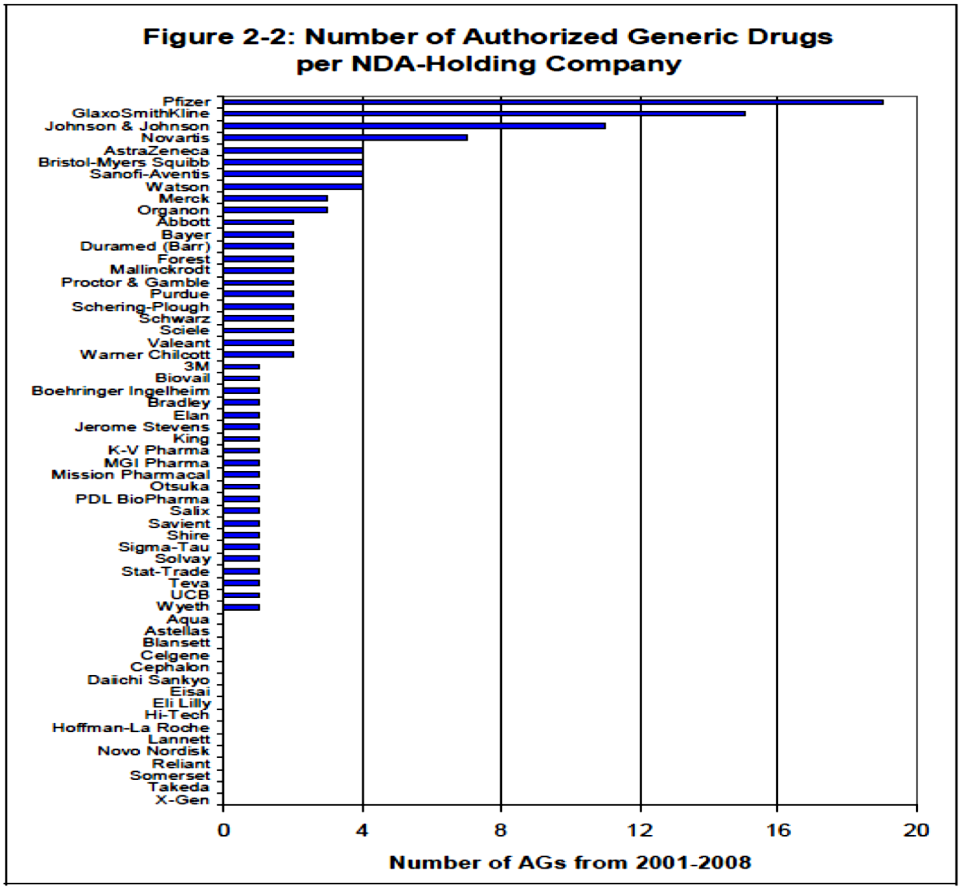
[51] FTC, Authorized Generic Drugs at vi (The Federal Trade Commission has concluded that, when free from competition from an authorized generic, "the first-filer's revenue will approximately double" during the first six months of generic competition, compared to what the first filer would make if it faced authorized generic competition.).

reasonably expect to earn if it faced competition from an AG during this 180-day period ($327.96 million - $94.744 million). Thus, AstraZeneca's agreement to not launch an AG for 6 months following Handa/Par's generic launch was a payment to Handa/Par of as much as approximately $233.216 million. The value of this payment to Handa/Par was tantamount to AstraZeneca handing this amount to Handa/Par in cash.

140. The same math and reasoning applies to Accord. Specifically, in exchange for Accord's commitment to not launch its generic version of 400mg strength Seroquel XR until November 1, 2016, AstraZeneca promised Accord that it would not launch an authorized generic version of 400mg strength Seroquel XR until May 1, 2017. AstraZeneca's sales of the 400mg strength of Seroquel XR in 2015 (the last full calendar year before generic Seroquel XR entry) were, and were expected to be, approximately $421 million. Using the same math as used for Handa/Par, the promise from AstraZeneca to Accord to not compete during Accord's 180-day exclusivity period was worth approximately $107.78 million.[52]

[52] Specifically, Accord's revenues without facing an AG would be expected to be $421 million * .5 * .8 * .9, or $151.56 million. Accord's revenues if it competed with an AG would be expected to be $421 million * .5 * .8 * .52 * .5, or $43.78 million. The difference is $107.78 million ($151.56 million - $43.78 million).

141. AstraZeneca often competes with first-filers by launching authorized generics. The FTC has found that, in the time period from 2001 to 2008, only four companies launched more authorized generics than AstraZeneca:[53]



142. On information and belief, AstraZeneca has launched authorized generics with respect to at least the following branded drugs: Accolate, Toprol-XL, Novaldex, Entocort EC, Pulmicort, Atacand, Plendil, Prilosec, and Nexium.

[53] FTC, Authorized Generic Drugs at 16 ("For each company, the graph includes all AGs marketed pursuant to the company's NDAs, whether marketed internally (e.g., by a subsidiary), or through an external generic partner.").

143. It is economically rational for a brand manufacturer that intends to compete for generic sales by launching an authorized generic to do so contemporaneously with the first ANDA filer's launch. This is because, during the first-filer's 180-day exclusivity, the only possible competitors for generic sales are the first-filer and the brand's authorized generic. No later-filing generic can launch during this time. As the Third Circuit observed, "Absent a no-AG promise, launching an authorized generic would seem to be economically rational for the brand." *King Drug Co. of Florence, Inc.*, 791 F.3d at 405.

144. Thus, it would have been economically rational for AstraZeneca to have launched authorized generic Seroquel XR contemporaneously with market entry by Handa/Par and Accord instead of *after* Handa/Par's and Accord's 180-day exclusivity periods. In the absence of the anticompetitive Non-Compete Agreements, AstraZeneca would have done so. Specifically, absent the Handa Non-Compete Agreement, AstraZeneca would have launched authorized generic Seroquel XR in the 50mg, 150mg, 200mg and 300mg strengths contemporaneous with Handa/Par's launch of generic Seroquel SR in these same strengths. Absent the Accord Non-Compete Agreement, AstraZeneca would have launched authorized generic Seroquel XR in the 400mg strength contemporaneous with Accord's launch of generic Seroquel XR in the 400mg strength.

145. Conversely, if there were no agreements preventing AstraZeneca from launching immediately upon Handa/Par's and Accord's launches, then AstraZeneca's waiting until Handa/Par's and Accord's 180-day exclusivity periods expired to launch authorized generic Seroquel XR was economically irrational. This is because there was no economically rational reason for AstraZeneca to forgo its AG Seroquel XR launches and competition with Handa/Par and Accord during Handa/Par's and Accord's 180-day exclusivity periods. During the 180-day exclusivity period, AstraZeneca was permitted to launch an authorized generic which would only have to compete with a single generic competitor in each strength. But after expiry of Handa/Par's and Accord's 180-day exclusivity periods, other generics could and would launch and AstraZeneca's AG would have to compete with those other generics too. Thus, it only made sense for AstraZeneca to forego its authorized generic launch during Handa/Par's and Accord's 180-day exclusivity periods as part of anticompetitive market-allocation or output-restriction agreements to compensate Handa/Par and Accord for delaying generic Seroquel XR competition.

146. The payments flowing from AstraZeneca to Handa/Par and to Accord via the Non-Compete Agreements' no-AG provisions had a cash value of as much as approximately $233.216 million to Handa/Par and $107.78 million to Accord. AstraZeneca intended that these payments would induce Handa/Par and Accord to

stay out of the market for Seroquel XR and its generic equivalents in return for sharing monopoly profits, a naked market allocation or output restriction agreement and thus a *per se* violation of the Sherman Act. But even under the rule of reason, the reverse payments from AstraZeneca to Handa/Par and Accord are large and unjustified, and Defendants had no procompetitive justification or other legitimate explanation for the payments. It is well established that there is no conceivable procompetitive justification for a covenant to delay the launch of authorized generics.

147. Absent AstraZeneca's unlawful reverse payments to Handa/Par and Accord, any agreement resolving AstraZeneca's patent infringement claim would have resulted in far less (or no) delay of Handa/Par's and Accord's generic Seroquel XR entry, generic competition would have been more robust, and generic prices would have been lower. But for the Non-Compete Agreements, Handa/Par and Accord would have launched their respective strengths of generic Seroquel XR earlier: during patent litigation (at risk), following a patent litigation victory, or pursuant to a negotiated entry date as part of an agreement that did not include reverse payments.[54] At the same time, AstraZeneca would have competed for generic

[54] As the Supreme Court stated, brand and generic companies can settle without reverse payments. "They may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *Actavis*, 570 U.S. at 158.

Seroquel XR sales by immediately launching authorized generic Seroquel XR instead of waiting to launch its authorized generic Seroquel XR for 6 months following Handa/Par's and Accord's generic launches.

148. On information and belief, and based on the fact that several Later-Filing Generics actually launched 180 days after Handa/Par and Accord, several other Later-Filing Generics had agreements with AstraZeneca that permitted entry upon Handa/Par's and Accord's launch, subject to Handa/Par's and Accord's 180-day exclusivity periods. Had Handa/Par and Accord launched their respective strengths of generic Seroquel XR earlier, those Later-Filing Generics would have launched earlier as well. But for the bottleneck of generic competition caused by the Non-Compete Agreements, and more specifically by those agreements' foreseeable and intentional effect of causing Handa/Par's and Accord's 180-day exclusivity periods to remain untriggered and thus unelapsed for up to five additional years, until November 1, 2016, one or more Later-Filing Generics, would have launched earlier, along with Handa/Par's generic, Accord's generic, and the authorized generic, lowering generic Seroquel XR prices further still.

149. The reason that Handa/Par and Accord did not launch earlier than November 1, 2016 had nothing whatsoever to do with any purported infringement risk flowing from the '437 Patent. Rather, Handa/Par's and Accord's generic launches were delayed by the anticompetitive Non-Compete Agreements, just as

Defendants understood and intended. In addition, Handa/Par and Accord, as the first ANDA filers for their respective strengths, had 180 days of regulatory exclusivity for those strengths during which no subsequent filer could launch an ANDA version of Seroquel XR. Thus, Handa/Par, Accord and AstraZeneca all recognized that delaying Handa/Par's and Accord's generic launches in exchange for no-AG covenants would benefit each of them. AstraZeneca would benefit by continuing to charge monopoly prices for Seroquel XR almost until the '437 Patent's expiry despite the weakness of the '437 Patent. This is because Handa and Accord were willing to be paid to delay their generic launches, and Handa/Par's and Accord's delay would delay the triggering, and thus the elapsing, of the Handa/Par's and Accord's 180-day exclusivity periods, thereby bottlenecking all generic Seroquel XR competition. Handa/Par and Accord benefitted by securing no-AG promises allowing them to be free from AG competition for the first six months after their delayed generic Seroquel XR launches.

150. According to information available publicly through the FDA, in addition to first-filers Handa/Par and Accord, at least 12 additional companies filed ANDAs to sell generic Seroquel XR:

Application No.	Company
209497	Alignscience Pharma Inc.
090757	Anchen
207655	Aurobindo Pharma Ltd.
202939	IntellipharmaCeutics Corp.
204203	Lupin Ltd.

Application No.	Company
204253	Macleods Pharmaceuticals Ltd.
202228	Mylan
208947	Novast Laboratories
201424	Osmotica
206260	Pharmadax Inc.
209635	Sciegen Pharmaceuticals Inc.
202377	Torrent

151. According to information available publicly through the FDA, many of these entities received final approval on or around the end of Handa/Par's and Accord's actual 180-day exclusivity periods. These included Pharmadax Inc., IntellipharmaCeutics Corp., Accord (as to the 150mg, 200mg and 300mg strengths), Par (as to the 400mg strength) and Lupin Ltd. These approvals would have been granted earlier if Handa/Par's and Accord's 180-day exclusivity periods had been triggered (and elapsed) earlier as a result of Handa/Par and Accord launching generic Seroquel XR earlier, which would have occurred absent AstraZeneca's payments to Handa/Par and to Accord to delay competition (*i.e.*, absent AstraZeneca's no-AG promises).

152. But for the Defendants' ongoing performance under the Non-Compete Agreements, generic competition for Seroquel XR, including competition from authorized generic Seroquel XR, would have occurred earlier, and prices for extended-release quetiapine fumarate would have been lower. But for Defendants' ongoing, illegal anticompetitive conduct, generic versions of Seroquel XR would

have become available much earlier – either through a Handa and/or Accord patent victory, at-risk launch, or agreement(s) that did not include unlawful payments for delay. Plaintiffs and other members of the Class would have paid lower prices for Seroquel XR and its generic equivalents. Defendants, by their conduct, have injured Plaintiffs and other members of the Class by causing them to pay millions of dollars in overcharges on their purchases of extended-release quetiapine fumarate.

VII. CONTINUING VIOLATIONS

153. This Complaint alleges a continuing course of conduct (including conduct within the limitations period), and Plaintiffs and members of the Class can recover for damages that they suffered during the limitations period. Accordingly, Plaintiffs' first class action complaint, filed on August 2, 2019, allows Class members to recover for all damages for the preceding four years.

VIII. ANTICOMPETITIVE EFFECT

154. The Non-Compete Agreements enabled Defendants to: (a) prevent and delay until November 1, 2016 the entry of less-expensive generic versions of Seroquel XR products in the United States; (b) fix, raise, maintain, or stabilize the price of Seroquel XR products; (c) allocate to AstraZeneca 100% of the U.S. market for Seroquel XR and its generic equivalents until November 1, 2016; (d) allocate to Handa/Par 100% of U.S. sales of the 50mg, 150mg, 200mg and 300mg strengths of generic Seroquel XR from November 1, 2016 through April 30, 2017; and (e)

allocate to Accord 100% of U.S. sales of the 400mg strength of generic Seroquel XR from November 1, 2016 through April 30, 2017.

155. Par launched generic 50mg, 150mg, 200mg, and 300mg strengths of Seroquel XR on November 1, 2016, thereby triggering its 180-day exclusivity period as to those strengths of generic Seroquel XR. Accord launched a generic version of the 400mg strength of Seroquel XR that same day, on November 1, 2016, thereby triggering its 180-day exclusivity period as to the 400mg strength of generic Seroquel XR. At least three Later-Filing Generics received final approval on or about May 9, 2017, shortly following the expiry of Par's and Accord's 180-day exclusivity periods.[55] AstraZeneca launched authorized generic Seroquel XR for all strengths (50mg, 150mg, 200mg, 300mg, and 400mg) at around the same time.[56]

156. But for the unlawful Handa Non-Compete Agreement, Handa/Par would have begun selling a less expensive generic version of the 50mg, 150mg, 200mg and 300mg strengths of Seroquel XR much earlier than November 1, 2016. Such sales would have occurred via market entry by Handa/Par upon a Handa/Par

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[55] *See Handa Pharmaceuticals, Inc. Announces FDA Approval for Generic Version of AstraZeneca's SEROQUEL XR® Extended Release Tablets*, https://handapharma.com/handa-pharmaceuticals-inc-announces-fda-approval-for-generic-version-of-astrazenecas-seroquel-xr-extended-release-tablets/.

[56] *Id*. *See also* DailyMed, LABEL: QUETIAPINE FUMARATE EXTENDED RELEASE, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7283b14f-023d-466f-a7eb-4356803d7c65&audience=consumer (showing AstraZeneca with a May 1, 2017 launch date as an "NDA Authorized Generic").

litigation victory, during patent litigation (at risk), or via a licensed entry in a settlement with AstraZeneca that did not include a no-AG provision or any other unlawful reverse payments from AstraZeneca to Handa/Par. In addition, contemporaneously with market entry by Handa/Par, AstraZeneca would have begun selling lower-priced authorized generic Seroquel XR in the 50mg, 150mg, 200mg and 300mg strengths in direct competition with the Handa/Par's generic. Other generic manufacturers would have launched generic Seroquel XR in the 50mg, 150mg, 200mg and 300mg strengths approximately 180 days after Handa/Par's launch.

157. Similarly, but for the illegal Accord Non-Compete Agreement, Accord would have begun selling a lower-price generic version of Seroquel XR in the 400mg strength earlier than November 1, 2016. Such sales would have occurred via market entry by Accord following a litigation victory, at-risk, or via a licensed entry in a settlement with AstraZeneca that did not include a no-AG provision or any other unlawful reverse payments from AstraZeneca to Accord. In addition, contemporaneously with market entry by Accord, AstraZeneca would have begun selling lower-priced authorized generic Seroquel XR in the 400mg strength in direct competition with Accord's generic. Other generic manufacturers would have launched generic Seroquel XR in the 400mg strength approximately 180 days after Accord's generic launch.

158. An increasingly competitive market for Seroquel XR and its generic equivalents, with lower prices, would have thereafter emerged as additional generic Seroquel XR products entered the market.

159. Defendants' unlawful concerted action has (a) delayed and suppressed the sale of generic Seroquel XR in the United States, (b) enabled AstraZeneca to sell Seroquel XR at artificially inflated, supracompetitive prices, (c) enabled Handa/Par and Accord to sell generic Seroquel XR, at artificially inflated, supracompetitive prices, and (d) caused Plaintiffs and the Class to pay supracompetitive prices for extended-release quetiapine fumarate tablets.

160. Thus, Defendants' unlawful conduct deprived Plaintiffs and the Class of the benefits of competition that the antitrust laws were designed to ensure.

IX. ANTITRUST IMPACT

161. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of brand and generic Seroquel XR directly from Defendants at supracompetitive prices. As a result of Defendants' illegal conduct, Plaintiffs and members of the Class were compelled to pay, and did pay, artificially inflated prices for their requirements for extended-release quetiapine fumarate. Those prices were substantially greater than the prices that Plaintiffs and members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of Seroquel XR was artificially inflated by Defendants' illegal conduct, and

(2) Plaintiffs and Class members were deprived of the opportunity to purchase lower-priced generic versions of Seroquel XR sooner, which they would have done had they had the opportunity. In addition, when generic versions of Seroquel XR were finally available, prices of generic Seroquel XR were higher than they would have been absent Defendants' unlawful conduct, and so Plaintiffs and the Class have incurred overcharges on their purchases of generic Seroquel XR as well.

162. As a consequence, Plaintiffs and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount of such damages will be calculated after discovery and upon proof at trial.

X. EFFECT ON INTERSTATE COMMERCE

163. At all material times, AstraZeneca, Par and Accord manufactured, promoted, distributed, and/or sold substantial amounts of brand and/or generic Seroquel XR in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States. During the relevant time period, in connection with the purchase and sale of brand and/or generic Seroquel XR, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

164. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Defendants as charged in this Complaint were within the flow of, and have substantially affected, interstate commerce.

XI. MONOPOLY POWER AND MARKET DEFINITION

165. At all relevant times prior to November 1, 2016, AstraZeneca had and maintained monopoly power in the market for Seroquel XR and its generic equivalents because it had the power to maintain the price of extended-release quetiapine fumarate at supracompetitive levels without losing substantial sales to other products prescribed and/or used for the same purposes of Seroquel XR so as to make the supracompetitive Seroquel XR price unprofitable.

166. Direct proof exists that AstraZeneca had monopoly power over the price of extended-release quetiapine fumarate. Such direct evidence includes, among other things, the high profit margin enjoyed by AstraZeneca on its Seroquel XR sales prior to entry of generic Seroquel XR and AstraZeneca's ability to profitably maintain the price of Seroquel XR well above competitive levels.

167. "[T]he 'size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power'—namely, the power to

charge prices higher than the competitive level."[57] And a firm that lacks monopoly power is not "likely to pay 'large sums' to induce 'others to stay out of its market.'"[58] AstraZeneca's anticompetitive reverse payments demonstrate that AstraZeneca enjoyed market and/or monopoly power with respect to Seroquel XR.

168. Manufacturers attempt to differentiate brand name drugs like Seroquel XR based on features and benefits (including safety and efficacy), not based on price. Doctors and patients are generally price-insensitive when prescribing and taking prescription drugs like Seroquel XR. This is due in part to the presence of insurance that bears much of the cost of prescriptions and other institutional features of the pharmaceutical marketplace. Different patients may respond differently to different drugs and even drugs within its same therapeutic class do not constrain the price of Seroquel XR. In addition, consumers do not choose prescription drugs directly; they must be prescribed by a physician who does not pay for the drug and may not be aware of its price. This "price disconnect" blunts price competition among different drugs, even if they are prescribed for similar conditions.

169. Other drugs that are not AB-rated to Seroquel XR do not exhibit substantial cross-price elasticity of demand with Seroquel XR, and thus are not economic substitutes for, nor reasonably interchangeable with, Seroquel XR.

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[57] *Actavis*, 570 U.S. at 157 (citation omitted).

[58] *Id*.

170. Products other than generic Seroquel XR are not economic substitutes for Seroquel XR or its generic equivalents, and the existence of other products used to treat depression, bipolar disorder, schizophrenia, or other illnesses treated by Seroquel XR did not significantly constrain AstraZeneca's pricing of Seroquel XR. On information and belief, AstraZeneca has never lowered the price of Seroquel XR in response to the pricing of other branded or generic drugs (other than generic Seroquel XR). AstraZeneca repeatedly and profitably raised Seroquel XR prices, by an average of 11% per year, over the period from when brand Seroquel XR launched through when generic Seroquel XR launched. Despite these repeated Seroquel XR price increases, Seroquel XR did not lose substantial sales to any product used to treat depression, bipolar disorder, schizophrenia, or other illnesses treated by Seroquel XR (other than generic Seroquel XR, when it launched). In addition, AstraZeneca repeatedly raised Seroquel XR prices without losing substantial sales to other products despite the launches of lower-cost, generic versions of other products approved to treat the same indications as Seroquel XR, including the 2012 launch of generic Seroquel IR (an immediate-release version of the same molecule as Seroquel XR) and the 2015 entry of generic Abilify (another drug approved to treat schizophrenia, depression, and bipolar disorder).

171. AstraZeneca needed to control only the sales of Seroquel XR and its generic equivalents, and no other products, in order to maintain the price of Seroquel

XR profitably at supracompetitive prices. Only the market entry of a competing, generic version of Seroquel XR would and did render AstraZeneca unable to profitably maintain its prices of Seroquel XR without losing substantial sales.

172. To the extent Plaintiffs are legally required to prove monopoly power circumstantially by first defining a relevant product market, the relevant product market is Seroquel XR (in all its forms and dosage strengths) and generic Seroquel XR (in all its forms and dosage strengths), or, equivalently, extended-release quetiapine fumarate. The relevant geographic market is the United States.

173. AstraZeneca's anticompetitive reverse payments to Handa/Par and to Accord demonstrate that AstraZeneca enjoyed market and/or monopoly power with respect to extended-release quetiapine fumarate tablets.

174. A small but significant non-transitory price increase above the competitive level for Seroquel XR by AstraZeneca would not cause a loss of sales sufficient to make the price increase unprofitable.

175. At competitive price levels, Seroquel XR does not exhibit significant positive cross-price elasticity of demand with any product other than generic Seroquel XR.

176. AstraZeneca, at all relevant times, enjoyed high barriers to entry with respect to competition to the above-defined relevant product market due to patent and other regulatory protections, and high costs of entry and expansion.

177. During the relevant period, Defendants' anticompetitive conduct has significantly damaged competition and consumers through a reduction of output and higher prices caused by an elimination or reduction of lower cost generic Seroquel XR throughout the United States.

178. AstraZeneca has maintained and exercised the power to exclude and restrict competition to Seroquel XR. AstraZeneca sold Seroquel XR at prices well in excess of marginal costs and substantially in excess of the competitive price, and enjoyed high profit margins.

179. At all relevant times prior to November 1, 2016, AstraZeneca's market share in the relevant market was 100%, implying substantial monopoly power.

XII. CLAIM ONE
VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 (AGREEMENT NOT TO COMPETE WITH BRAND AND GENERIC SEROQUEL XR 50MG, 150MG, 200MG AND 300MG STRENGTHS) AGAINST ASTRAZENECA, HANDA AND PAR

180. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

181. Defendants have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

182. On or about September 29, 2011, when the Handa Non-Compete Agreement was executed, and at times prior to the formal execution thereof,

Defendants entered into an illegal contract, combination and conspiracy in restraint of trade under which AstraZeneca agreed to make a large reverse payment to Handa/Par in exchange for Handa/Par's agreement to delay bringing its 50mg, 150mg, 200mg and 300mg strengths (the "Handa/Par Strengths") of generic Seroquel XR to the market for up to 5 years. The purpose and effect of the Handa Non-Compete Agreement was to: (a) allocate to AstraZeneca 100% of the U.S. sales of extended-release quetiapine fumarate for the Handa/Par Strengths until November 1, 2016; (b) delay the availability of generic Seroquel XR in the Handa/Par Strengths in the United States, thereby protecting Seroquel XR from any generic competition in those strengths until November 1, 2016; (c) delay the entry of AstraZeneca's authorized generic in the Handa/Par Strengths until May 1, 2017, 180 days after Handa/Par's generic entry in the Handa/Par Strengths, and allocate to Handa/Par 100% of U.S. sales of generic extended-release quetiapine fumarate for the Handa/Par Strengths prior to that time; and (d) fix and maintain, at supracompetitive levels, the price Plaintiffs and Class members paid for extended-release quetiapine fumarate in the Handa/Par Strengths.

183. Par joined the illegal contract, combination and conspiracy in restraint of trade during its pendency when Par acquired Handa's ANDA and Handa assigned the Handa Non-Compete Agreement to Par. Par then further participated in the illegal contract, combination and conspiracy in restraint of trade by performing and

abiding by the unlawful Handa Non-Compete Agreement, by selling generic Seroquel at supracompetitive prices, and by dividing the ill-gotten gains with Handa.

184. The Handa Non-Compete Agreement harmed Plaintiffs and the Class as set forth above.

185. Defendants are jointly and severally liable for the Handa Non-Compete Agreement under either the *per se* standard or the rule of reason standard.

186. There is and was no legitimate, non-pretextual, procompetitive justification for the payment from AstraZeneca to Handa/Par that outweighs its harmful effect. Even if there were some conceivable such justification, the payment was not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

187. As a direct, proximate, foreseeable, and intended result of Defendants' agreement in restraint of trade, as alleged herein, Plaintiffs and the Class were harmed and suffered overcharge damages as aforesaid.

XIII. CLAIM TWO
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE AS TO BRAND AND GENERIC SEROQUEL XR 50MG, 150MG, 200MG AND 300MG STRENGTHS) AGAINST ASTRAZENECA, HANDA AND PAR

188. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

189. At all relevant times prior to November 1, 2016, AstraZeneca possessed substantial market power (*i.e.*, monopoly power) in the relevant market. AstraZeneca possessed the power to control and maintain prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

190. Through the Handa Non-Compete Agreement, AstraZeneca, Handa and Par conspired to unlawfully maintain AstraZeneca's monopoly power in the relevant market by agreeing to block and delay market entry of generic Seroquel XR in the Handa/Par Strengths.

191. The Handa Non-Compete Agreement (a) allocated to AstraZeneca 100% of the U.S. sales of extended-release quetiapine fumarate in the Handa/Par Strengths until November 1, 2016; (b) delayed the availability of generic versions of Seroquel XR in the Handa/Par Strengths in the United States, thereby protecting Seroquel XR in the Handa/Par Strengths from any generic competition until November 1, 2016; (c) delayed the entry of AstraZeneca's authorized generic in the Handa/Par Strengths until May 1, 2017, 180 days after Handa/Par's generic entry in the Handa/Par Strengths, and allocated to Handa/Par 100% of the U.S. sales of generic extended-release quetiapine fumarate in the Handa/Par Strengths prior to that time; and (d) fixed and maintained, at supracompetitive levels, the price Plaintiffs and Class members paid for extended-release quetiapine fumarate in the Handa/Par Strengths.

192. The goal, purpose and/or effect of the Handa Non-Compete Agreement was to maintain, enhance, and extend AstraZeneca's monopoly power, in violation of Sherman Act Section 2, 15 U.S.C. § 2. The Handa Non-Compete Agreement was intended to and did prevent and/or delay generic competition to Seroquel XR in the Handa/Par Strengths and enabled AstraZeneca to continue charging supracompetitive prices for Seroquel XR in the Handa/Par Strengths without a substantial loss of sales.

193. Defendants knowingly and intentionally conspired to maintain, enhance, and extend AstraZeneca's monopoly power in the relevant market.

194. Defendants specifically intended that the Handa Non-Compete Agreement would maintain AstraZeneca's monopoly power in the relevant market, and injure Plaintiffs and the Class thereby.

195. Defendants each committed at least one overt act in furtherance of the conspiracy.

196. As a direct, proximate, foreseeable, and intended result of Defendants' concerted monopolistic conduct, as alleged herein, AstraZeneca unlawfully maintained, enhanced, and extended its monopoly power and Plaintiffs and the Class were harmed and suffered overcharge damages as a result, as alleged herein.

XIV. CLAIM THREE
VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 (AGREEMENT NOT TO COMPETE WITH BRAND AND GENERIC SEROQUEL XR 400MG STRENGTH) AGAINST ASTRAZENECA

197. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

198. AstraZeneca, with Accord, engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

199. On or about October 5, 2011, when the Accord Non-Compete Agreement was executed, and at times prior to the formal execution thereof, AstraZeneca entered into an illegal contract, combination and conspiracy in restraint of trade under which AstraZeneca agreed to make a large reverse payment to Accord in exchange for Accord's agreement to delay bringing its 400mg strength (the "Accord Strength") of generic Seroquel XR to the market for up to 5 years, the purpose and effect of which was to: (a) allocate to AstraZeneca 100% of the U.S. sales of extended-release quetiapine fumarate for the Accord Strength until November 1, 2016; (b) delay the availability of generic Seroquel XR in the Accord Strength in the United States, thereby protecting Seroquel XR from any generic competition until November 1, 2016; (c) delay the entry of AstraZeneca's authorized generic in the Accord Strength until May 1, 2017, 180 days after Accord's entry with generic Seroquel XR in the Accord Strength, and allocate to Accord 100% of U.S.

sales of generic extended-release quetiapine fumarate for the Accord Strength prior to that time; and (d) fix and maintain, at supracompetitive levels, the price Plaintiffs and Class members paid for extended-release quetiapine fumarate in the Accord Strength.

200. The Accord Non-Compete Agreement harmed Plaintiffs and the Class as set forth above.

201. AstraZeneca is jointly and severally liable for the Accord Non-Compete Agreement under either the *per se* standard or the rule of reason standard.

202. There is and was no legitimate, non-pretextual, procompetitive justification for the large payment from AstraZeneca to Accord that outweighs its harmful effect. Even if there were some conceivable such justification, the payment (the no-AG provision) was not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

203. As a direct, proximate, foreseeable, and intended result of the unlawful Accord Non-Compete Agreement, as alleged herein, Plaintiffs and the Class were harmed and suffered overcharge damages as alleged herein.

XV. CLAIM FOUR
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE AS TO BRAND AND GENERIC SEROQUEL XR 400MG STRENGTH) AGAINST ASTRAZENECA

204. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

205. At all relevant times prior to November 1, 2016, AstraZeneca possessed substantial market power (i.e., monopoly power) in the relevant market. AstraZeneca possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

206. Through the Accord Non-Compete Agreement, AstraZeneca conspired with Accord to maintain, enhance, and extend AstraZeneca's monopoly power in the relevant market by agreeing to block and delay market entry of generic Seroquel XR in the Accord Strength.

207. The Accord Non-Compete Agreement (a) allocated to AstraZeneca 100% of the U.S. sales of extended-release quetiapine fumarate in the Accord Strength until November 1, 2016; (b) delayed the availability of generic versions of Seroquel XR in the Accord Strength in the United States thereby protecting Seroquel XR in the Accord Strength from any generic competition until November 1, 2016; (c) delayed the entry of AstraZeneca's authorized generic in the Accord Strength until May 1, 2017, 180 days after Accord's generic entry in the Accord Strength, and allocated 100% of U.S. sales of generic extended-release quetiapine fumarate in the Accord Strength to Accord prior to that time; and (d) fixed and maintained, at supracompetitive levels, the price Plaintiffs and Class members paid for extended-release quetiapine fumarate in the Accord Strength.

208. The goal, purpose and/or effect of the Accord Non-Compete Agreement was to maintain, enhance, and extend AstraZeneca's monopoly power, in violation of Sherman Act Section 2, 15 U.S.C. § 2. The Accord Non-Compete Agreement was intended to and did prevent and/or delay generic competition to Seroquel XR in the Accord Strength and enabled AstraZeneca to continue charging supracompetitive prices for Seroquel XR in the Accord Strength until November 1, 2016 without a substantial loss of sales.

209. AstraZeneca knowingly and intentionally conspired, with Accord, to maintain, enhance, and extend AstraZeneca's monopoly power in the relevant market.

210. AstraZeneca specifically intended that the Accord Non-Compete Agreement would maintain AstraZeneca's monopoly power in the relevant market, and injured Plaintiffs and the Class thereby.

211. As a direct, proximate, foreseeable, and intended result of the Accord Non-Compete Agreement, as alleged herein, AstraZeneca unlawfully maintained, enhanced, and extended its monopoly power and Plaintiffs and the Class were harmed as a result, as alleged herein.

XVI. CLAIM FIVE
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (MONOPOLIZATION AND MONOPOLISTIC SCHEME) AGAINST ASTRAZENECA

212. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

213. At all relevant times prior to November 1, 2016, AstraZeneca possessed substantial market power (i.e., monopoly power) in the relevant market. AstraZeneca possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

214. By entering into the Handa Non-Compete Agreement and the Accord Non-Compete Agreement, AstraZeneca willfully and intentionally maintained, enhanced, and extended its monopoly power using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiffs and the Class thereby. Specifically, AstraZeneca (a) allocated to itself 100% of the market for extended-release quetiapine fumarate in all strengths in the United States until November 1, 2016; (b) delayed the availability of generic versions of Seroquel XR in all strengths in the United States, thereby protecting Seroquel XR in all strengths from any generic competition until November 1, 2016; (c) delayed the entry of its authorized generic in all strengths for 180 days after Par's and Accord's entry with generic Seroquel XR products, until May 1, 2017, and allocated 100% of U.S. sales of generic extended-release quetiapine fumarate in the Handa/Par

Strengths to Handa/Par and 100% of U.S. sales of generic extended-release quetiapine fumarate in the Accord Strength to Accord prior to May 1, 2017; and (d) fixed and maintained, at supracompetitive levels, the price Plaintiffs and Class members paid for extended-release quetiapine fumarate.

215. It was AstraZeneca's conscious object to further its dominance in the relevant market by and through the anticompetitive conduct alleged herein.

216. AstraZeneca's anticompetitive conduct harmed competition as alleged herein.

217. As a direct, proximate, foreseeable, and intended result of AstraZeneca's illegal and monopolistic conduct, AstraZeneca unlawfully maintained, enhanced, and extended its monopoly power, and Plaintiffs and the Class were harmed as a result, as alleged herein.

XVII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of itself and the proposed Class, pray for judgment against all Defendants, jointly and severally, as follows:

218. That the Court determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class, and declare the Plaintiffs as the representatives of the Class;

219. That the Court adjudge and decree that each of the Defendants has violated Sections 1 and 2 of the Sherman Antitrust Act;

220. That the Court enter joint and several judgments against each of the Defendants and in favor of Plaintiffs and the Class;

221. That Plaintiffs and all others similarly situated be awarded damages, in an amount to be determined at trial, including post-judgment interest, suffered by reason of Defendants' violations and that those damages be trebled in accordance with the law;

222. That Plaintiffs and the Class be awarded reasonable attorneys' fees and costs as provided by law; and

223. Such other and further relief as the Court may deem just and proper.

XVIII. JURY TRIAL DEMANDED

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury of all claims and complaints in this Complaint so triable.

[SIGNATURE PAGE FOLLOWS]

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Respectfully submitted,

/s/ Michael Van Gorder

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